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14. ABSTRACT The Pacific Pediatric Advanced Care Initiative established an advanced care Center with extracorporeal life support (ECLS) support in Hawaii to support the Pacific Rim. The Center has a goal to advance the science of Pediatric Advanced Care through new basic science and simulation research, while providing advanced care to patients, and improving the education and training of Department of Defense (DOD) Health Care providers. The Center has been established and evaluated through existing guidelines for clinical care and education and training. The initial research foci for the Center was the following: 1. basic science research in extracorporeal membrane oxygenation (ECMO), 2. development of manikin-based, simulation technologies as applied to the ECLS curriculum, 3. develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.					
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Introduction

The Pacific Pediatric Advanced Care Initiative has established an advanced care center with extracorporeal life support (ECLS) support in Hawaii to support the Pacific Rim. The Center's goal is to advance the science of Pediatric Advanced Care through new basic science and simulation research, while providing advanced care to patients, and improving the education and training of Department of Defense (DOD) Health Care providers. The Center has been evaluated through existing guidelines for clinical care and education and training. The major research foci for the Center included: 1. basic science research in extracorporeal membrane oxygenation (ECMO), and 2. development and evaluation of simulation technologies as applied to pre-ECLS and ECLS curricula. This initiative was a joint venture between Tripler Army Medical Center (TAMC), Kapi'olani Medical Center for Women and Children (KMCWC), Kaiser Permanente Hawaii, University of Hawaii (UH), and the University of Pittsburgh Medical Center (UPMC). The objectives during this contracting period were as follows:

1. Establish a new Center for extracorporeal life support in Hawaii. Ongoing clinical review of results was conducted to ensure that patient care meets national ECLS benchmarks. ECLS is established and proven standard-of-care technology, which provides advanced levels of care to Pediatric patients with life-threatening, potentially reversible cardiorespiratory failure. In preplanning, it was determined by the consortium that this program would be housed at Kapi'olani Medical Center for Women and Children and jointly staffed by physicians from Tripler, Kaiser, and Kapi'olani.
2. Name a national advisory board. The advisory board functioned as an oversight panel, and was instrumental in providing the clinical and educational experts that helped to review the administrative, clinical and educational programs to insure the Center is meeting national guidelines and benchmarks.
3. Develop a basic science research program for the Center. The first study evaluated the utility of ECMO for management of severe septic shock in a porcine model, and whether the utilization of blood substitutes would impact results. Hormonal and physiologic parameters were measured, combined with qualitative histologic analyses of end organs. The program aimed to help advance the science of ECLS, while providing the groundwork for future Center studies.
4. Develop a manikin-based simulator training curriculum to supplement to traditional training. This training curriculum aimed to serve multiple levels of health care providers to include physicians, nurses, perfusionists, and respiratory therapists. Following didactic education, skill acquisition rates of defined tasks and infant simulator survival were compared both with and without manikin training.
5. Develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data. Patient physiologic variables are affected by pharmacologic and ECMO pump settings. Connecting these interactions through a computer simulation model will provide a valuable training resource for ECMO centers with small case numbers. ECMOjo was refined using a heuristic evaluation model. Following prototype finalization, scenario-based curriculum was evaluated on its ability for providers to acquire ECMO skills.

Body

Task 1. To establish a new Hawaii-Pacific Rim extracorporeal life support (ECLS) Center, which provides advanced levels of care to Pediatric patients with life-threatening cardiorespiratory failure; to evaluate the Center's effectiveness in attaining clinical results that meet national ECLS benchmarks.

a. Establish ECLS Hanuola Center at Kapi'olani Medical Center for Women and Children using well-established clinical and referral guidelines, and training curricula.

a.1. ECMO Cases

Currently, case load for the civilian sector has averaged five to six cases annually, with the Center expected to grow to 12 cases per year into the future. Since the opening of the Hanuola ECMO Center, there have been 68 ECMO consults (25 consults in 2008, 22 consults in 2009, 21 consults in 2010), with 21 patients being treated with ECMO (five patients in 2008, five patients in 2009, 11 patients in 2010). The caseload at the Hanuola Center falls within the range of average cases for ECMO centers across the US. According to the ELSO database, of the 96 centers that reported patients in 1997, the average number of patients per center was nine (Roy, 2000). See Appendix A.1 for ELSO results for the Hanuola Center, and Appendix A.2 for the ECLS Registry Report for the Center.

a.2. Policies and Procedures

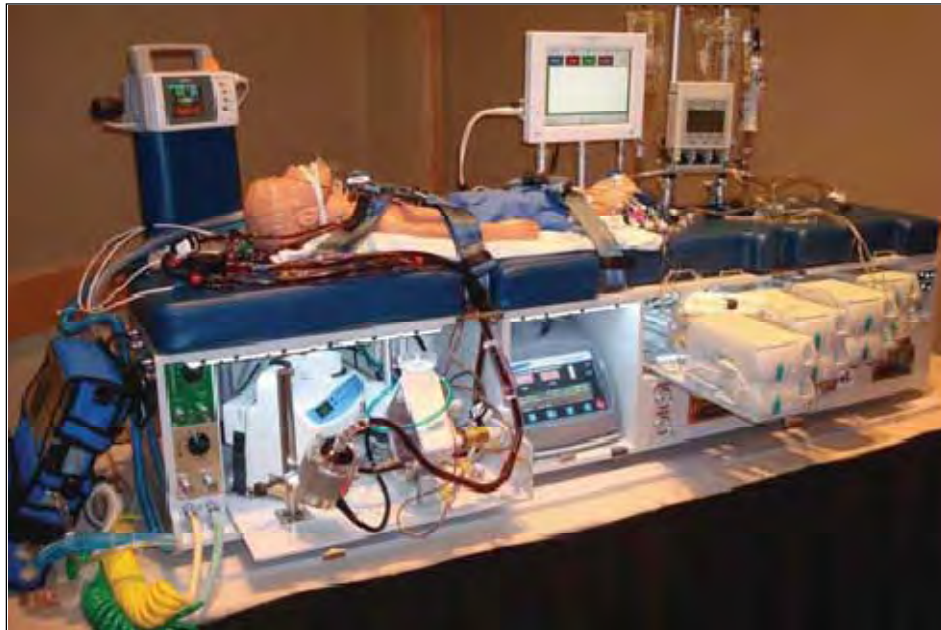
The Hanuola Center has worked closely to integrate with several departments and programs at KMCWC. These include the blood bank, blood utilization committee, clinical laboratories, operating room, central supply, pharmacy, respiratory care, Neonatal Intensive Care Unit (NICU) nursing, Pediatric Intensive Care Unit (PICU) nursing, Risk Management and the Pediatric Executive Committee. The development of policies and procedures with other supporting clinical departments has been completed. The Hanuola Center will continue with monthly ECMO meeting beyond this contracting period (funded by KMCWC) to facilitate ongoing discussion of patient debriefs, system review and educational updates.

a.3. ECMO Transport

During the first year of the Hanuola Center, the need for air and ground ECMO transport systems became a priority due to the unique clinical circumstances of the Hawaii medical community. In order to develop an ECMO transport system extensive planning and coordination of experienced personnel was necessary. The nature of transporting pediatric ECMO patients is often associated with severe instability and possible cardiac arrest. Thus, collaboration with AirMed International and Elliott Aviation was initiated to design and build the ECMO Transport Sled (ETS).

Elliott Aviation began construction of the ECMO Transport Sled in mid December 2009 to facilitate the FAA approval process. Construction is at Elliott's expense. The sled was completed in early 2010, whereby Federal Aviation Administration (FAA) approval was sought. The FAA has determined that the ETS did not need a Supplemental Type Certificate to clear it for flight; only the medical base in the aircraft needed a modification of its Certificate in order to

transport the ETS. The ETS received structural substantiation for the Hawker Beechjet 400A aircraft from the FAA in March 2010. The paperwork (form 8110-3) is on file with Elliott Aviation and Hanuola. Transport Protocols have been developed based on existing KMCWC Transport Protocols. Equipment and Supply checklists have been completed as well as power and weight charts. In December 2010, the ETS was purchased from Elliott Aviation and made available to the Hanuola Center for ECMO air and ground transport.



This is a significant milestone since ECMO transport over the open ocean presents many interesting challenges for both the medical team and the transport modality. Prolonged isolation from medical facilities, power limitations, and aircraft space limitations are the most formidable. In addition, long flight times carry an increased risk for multiple patient interventions, equipment malfunction, and medical supply depletion. A high degree of coordination between the various entities involved is essential to avoid critical consequences. Thus successfully designing and constructing an ECMO Transport Sled will better facilitate the ability to transfer critically ill patients via ground and air.

a.4. Credentialing

As part of a functioning ECLS Center, proper credentialing was necessary for management of the ECMO program. A number of physicians have been granted privileges to provide routine and emergency clinical care for infant patients on ECLS. This included 12 Neonatal physicians and 6 Pediatric Critical Care physicians. Eight physicians have been granted privileges to independently select appropriate patients for ECLS; to oversee cannulation and decannulation procedures; and participate in daily and emergency management. During this contracting period, all pediatric intensive care unit physicians and staff have been certified, and certification of all pediatric surgeons for Level 2 credentials has been completed.

a.5. Website

In addition to the clinical services provided by the Hanuola Center, a website has been developed to provide information to physicians, patients, families and the general public about ECMO and the Center. This website serves as a portal to the Hanuola ECMO Training courses, training manual and lectures. During the final year of this contract, the website has been updated with staff list and contact information and Hanuola Training Course lectures. Going beyond this contracting period, the website will be housed, maintained and funded by KMCWC in support of the Hanuola Center.

b. Conduct ongoing training, including didactic, wet labs, and animal labs based on well-established models.

In order to maintain the competency of ECLS providers, a training system has been established to augment clinical experience. Training guidelines are well defined by ELSO (ELSO Guidelines; ECMO Specialist Manual, 1999): didactics, wet-labs, animal labs, bedside teaching, and transport training (land, and air if appropriate). ECMO pump experience is obtained through animal laboratories and wet labs. This “hands-on” experience is particularly important for Centers with small clinical volumes, where clinical case experience used for education and training is limited and must be supplemented by such training. This training curriculum at the Hanuola Center has served multiple levels of health care providers including physicians, nurses, perfusionists, respiratory therapists and other ancillary staff members.

The Hanuola Center has established a schedule of refresher courses, 4 hours each, to maintain ECMO competency for nurses, respiratory therapists and other ancillary staff members who have already completed the ECMO training course. Dates of the courses that have been held throughout the contracting period include the following: January, March, June, and October 2008; May, September, October and November 2009; and May 2010. In July 2010, a perfusion competency was completed using high fidelity manikin simulation.

The animal training lab that has been developed serves as the primary training platform for ECLS provider training using previously established models. Using a validated model established at the only other DOD ECLS center, Wilford Hall Air Force Medical Center, an animal training model has been developed to provide a method of competency acquisition and skills maintenance for ECLS providers. Evaluation of bedside and emergency skills competency in the Animal Lab has been adapted from the Children’s Healthcare of Atlanta training course. Tripler Army Medical Center’s large animal research laboratory is the only such facility in the State of Hawaii that is federally approved for this type of training. It is under veterinary management employing strict animal use guidelines. TAMC lab technicians are now able to operate ECMO system independently without perfusion support.

The first animal lab was coordinated and successfully conducted on 30 August 2007 at TAMC. Porcine blood was collected the day before and stored overnight without any problems. Subsequent animal labs have been conducted in January, March, May, June and October of 2008; October 2009; and May 2010. Training labs emphasize routine and emergent clinical skills with emphasis on communication. Participants include physicians, nurses, respiratory specialists and perfusionists. Outline objectives and specific curriculum have been completed for future ECMO Training Courses and clinical lab training beyond this contracting period.

c. Conduct ongoing evaluation of clinical results against national benchmarks using established methodology.

The Extracorporeal Life Support Organization (ELSO) was established in 1989. The organization oversees and maintains the registry, promotes education and training materials in support of ECLS, and stimulates ongoing research (ELSO, 2005). One of the major functions of the ELSO is to maintain a Registry comprised of all known cases in which ECLS was performed (ELSO 2008). Aggregate data serves as national benchmarks and are evaluated to enhance extracorporeal support technology and the technique of ECLS.

The Hanuola ECMO Center has continued to submit detailed data to the ELSO registry through the data forms (See Appendix A.2). As seen in the Appendix as previously reported, Hanuola ECMO Center compared favorably to ELSO standards.

d. Name and convene a National Advisory Board for Center review as part of an annual review meeting.

As part of the Hanuola Center, a National Advisory Board was selected. The purpose of the National Advisory Board was to function as an oversight panel, which provides the clinical and educational experts to help review the administrative, clinical and educational programs. This has insured the Center met national guidelines and benchmarks. The Board met annually as part of the Center's annual review meeting. The membership of the advisory board throughout the contracting period included:

- Devn Cornish, MD – Vice Chairman of Faculty Development in Pediatrics, Emory University Medical School
- Denise Suttner, MD – Director, San Diego Regional ECMO Program.
- John Lin, MD – Pediatric Intensivist, Brooke Army Medical Center
- Michael Heard, RN –Egleston Children's Hospital at Emory University
- William Harris, CCP – Ochsner Clinic, New Orleans
- Melissa McNeil, MD – Education Advisor, University of Pittsburg Medical Center
- Donald McCurnin, MD (*new*) – ECMO Program Director , University of Texas Southwestern Medical Center

Going into the future, as is standard practice in the ELSO community, the Hanuola Center will seek expert consultation from established ECMO centers and ELSO community experts via personal contact and the ECLS network, as needed on a case by case basis.

Task 2. To conduct basic science research to advance scientific knowledge in ECLS.

a. Renovate animal operating suite, to be scheduled around training and research

A Dedicated animal operating suite at Tripler Army Medical Center Department of Clinical Investigation for ECMO research studies was established in 2007 including equipment and renovations to accommodate the laboratory. The ECMO System was made available to University of Hawaii Clinical Training Wet Labs or Pediatric ECMO Center at Kapi'olani

Medical Center for Women and Children on an as needed basis for just in time training, and for the regular training that was discussed in Task 1.b above.

b. Conduct Center's first basic science research protocol after appropriate IRB approvals

Initial research protocol was approved in March 2007 and research execution started in fall 2007. This initial protocol has spawned 2 additional ECMO protocols and 2 additional grant awards from other source, totaling \$1.1M. Thus, in addition to advancing the science of ECMO delivery, this initial project has provided the groundwork for future Hanuola Pacific Pediatric Advanced Care Center studies from other funding sources. This first study has also contributed to the training mission of Tripler Army Medical Center's Graduate Medical Education program by creating a line of research for surgery residents and neonatology fellows that has resulted in national recognition awards for their respective research programs.

Results of experiments proposed in Specific Aim 2 of the grant proposal are presented below, aligned with the initial Hypothesis Statements.

Specific Aim 2. Conduct basic science research to advance scientific knowledge in ECLS.

In this study we tested the hypothesis that ECMO is an effective therapy for tissue preservation and maintenance of organ function in a porcine model of endotoxin-induced septic shock. Endotoxic shock was induced, and hormonal and physiologic parameters prior to ECMO and during ECMO therapy were compared. The original objectives of this study have been addressed and this project has successfully yielded clinically relevant and important data that supports clinical guidelines for the use of Extracorporeal Membrane Oxygenation in the treatment of septic shock.

The experimental protocol for comparing ECMO affects in control and endotoxic shock conditions can be seen in Figure 1. Pigs were sedated and anesthetized with pentobarbital throughout the experiment. After catheters were placed, a 90-min baseline period was allowed. In control group animals, ECMO was then started and measurements were taken at an early phase of ECMO (within 30 of ECMO initiation) and a later phase after ECMO steady state was established for 2 hours. ECMO flow rates (0.7-1.0 L/min) were adjusted to maintain mean arterial pressure (MAP) and cardiac output (CO) at baseline levels. In septic shock group animals, after baseline measurements were obtained, endotoxic shock was induced with an i.v. injection of 3-30 mg/kg of *E. coli* endotoxin to achieve a stable hypotension. Blood samples for hormone measurements and regional blood flow (RBF) assessments were obtained with different colored microspheres injected into the left ventricle prior to endotoxic shock (at baseline), during pre-treatment shock, and during established ECMO treatment. Hemodynamic measurements were recorded continuously throughout the experiment.

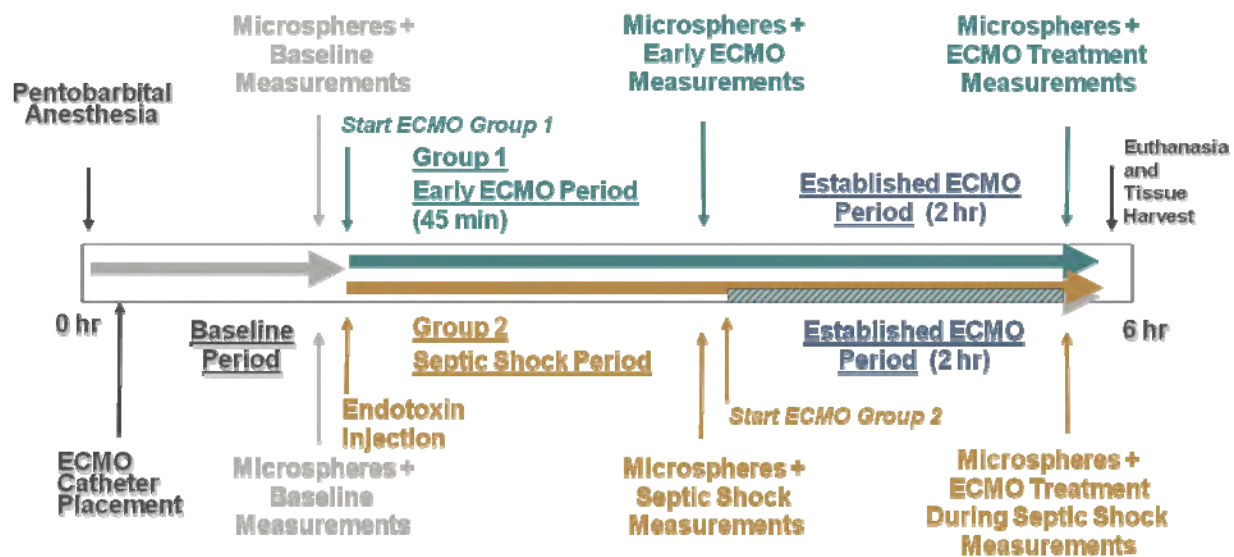


Figure 1. Experimental protocol

The percent of total perfusion delivered by the native heart while on ECMO (Figure 2) was determined by measuring cardiac output (CO) via a Swan Ganz catheter thermistor placed in the abdominal aorta and cold thermodilution vehicle injected into the ECMO circuit immediately at the flow delivery site into the aortic arch. The difference between total flow and ECMO pump flow was attributed to native heart cardiac output.

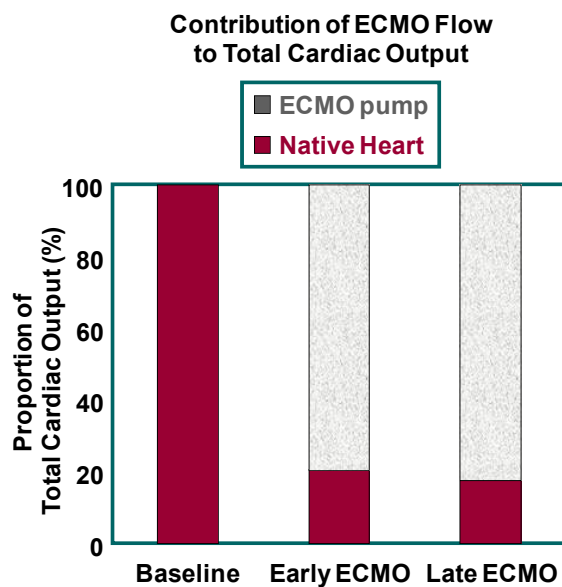


Figure 2. Total perfusion delivered by native heart and ECMO pump.

Research accomplishments associated with the Specific Hypotheses of the original proposal are as follows:

Hypothesis A: To characterize the cardiovascular and endocrine responses to ECMO after establishment of endotoxin-induced septic shock

Cardiovascular responses to ECMO. In control animals, MAP and total systemic CO were maintained by ECMO in all three periods (Figure 3). Endotoxin caused a 40% decrease in MAP, CO, and oxygen delivery compared to baseline ($p<0.05$). During endotoxin, ECMO was able to prevent further deterioration of MAP but did not fully return CO to baseline levels. ,

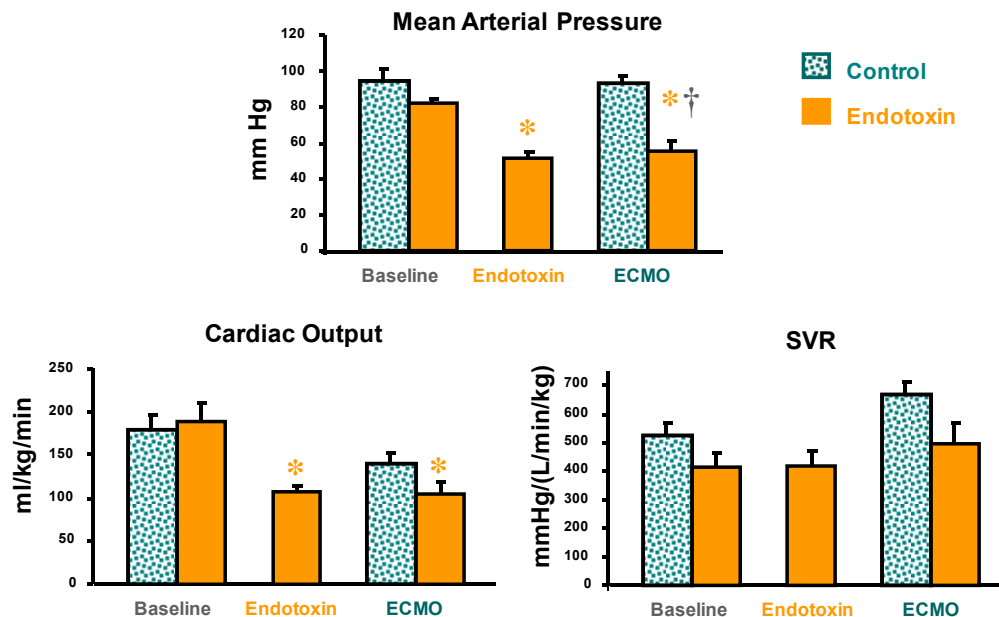


Figure 3. ECMO effects on hemodynamics during endotoxic shock. In the septic shock group, endotoxin caused a sustained systemic hypotension. ECMO prevented further deterioration of MAP but did not fully return flow to pre-endotoxin levels. (* = different from baseline, $p<0.05$; † = different from untreated endotoxin, $p<0.05$)

The optimal perfusion settings and blood pressure target levels for ECMO flow were not yet defined so we examined whether setting ECMO flows to maintain pre-ECMO baseline blood pressure adequately perfused vital organs such as the brain. Results demonstrated that all areas of brain were equally perfused (Figure 4). However, ECMO delivers proportionately more blood flow to the brain when adjusting ECMO pump flow to achieve stable MAP. Whether the increased flow to brain has long term detrimental effects is unknown. A concern is that excessive brain perfusion while on ECMO may cause intracranial hemorrhage. Results indicate that perhaps ECMO perfusion settings should be adjusted according to brain blood flow and oxygen delivery versus systemic pressure criteria.

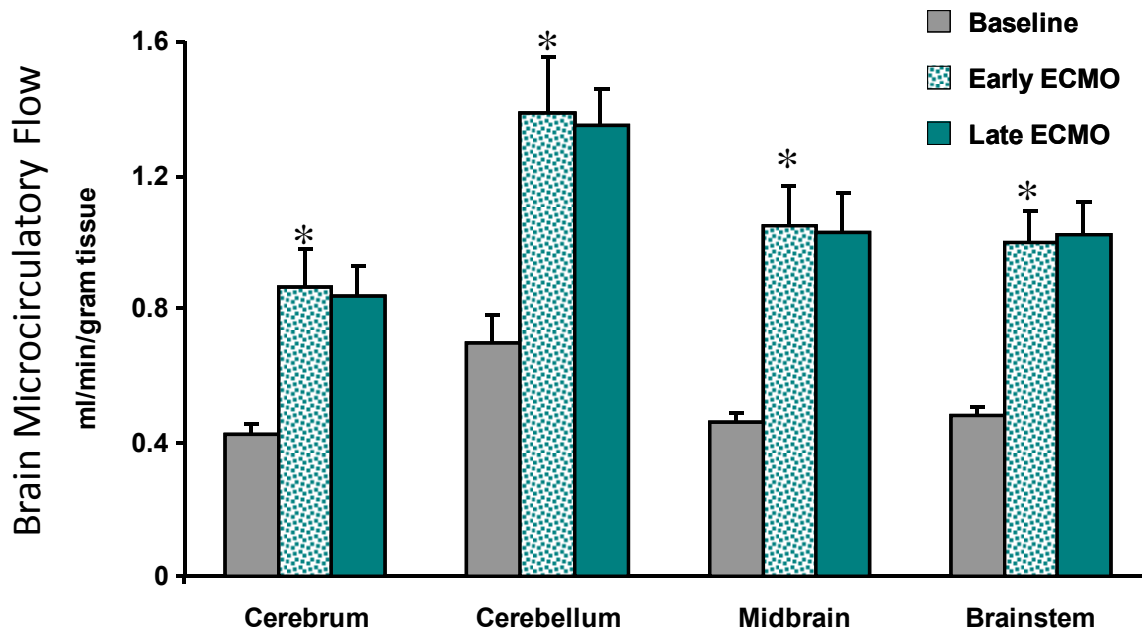


Figure 4. Brain microcirculatory flow in healthy control pigs at baseline, 30 minutes after ECMO, and after 2 hours on ECMO. There was a significant increase in perfusion immediately after initiation of ECMO despite keeping MAP constant with ECMO delivery. The increase in perfusion was seen in all brain regions (* = different from baseline, $p < 0.05$)

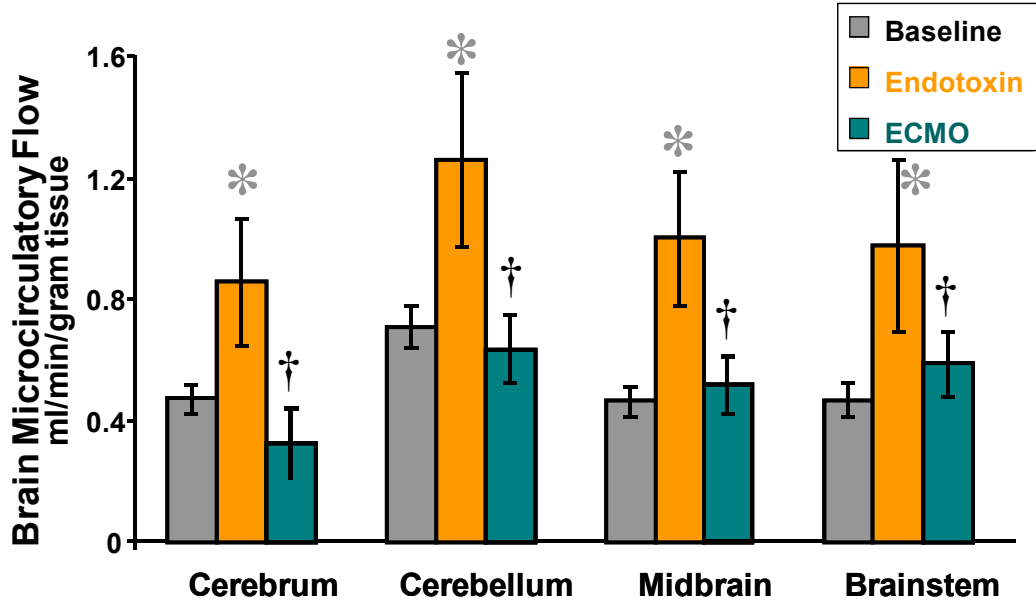


Figure 5. Brain microcirculatory flow in endotoxin-exposed pigs at baseline, after endotoxin-induced shock, and ECMO during shock. Blood flow increased to all regions of the brain during endotoxic shock. Treatment with ECMO returned blood flow to baseline levels. (*=different from baseline, $p < 0.05$; †=different from untreated endotoxin period pre-ECMO, $p < 0.05$)

Endocrine responses to ECMO. We examined endocrine profiles before and during ECMO because redirection of regional blood flow to vital organs is regulated differently by the different cardiovascular hormones (Uyehara, 2005). In both control and endotoxemic animals, ECMO caused a decrease in vasopressin (VP) (Figure 6), cortisol, adrenocorticotropic hormone (ACTH) and dopamine which could be attributed to a dilutional effect caused by endogenous hormone production not adjusting to the incorporation of a large circuit volume during ECMO. However, not all hormones decreased. The endotoxin-induced drop in MAP increased renin, which was reversed with ECMO treatment. Interestingly, aldosterone levels did not decrease, and sodium levels tended to increase with ECMO in either control or endotoxemic animals.

ECMO causes similar endogenous hormonal profile shifts in both control and endotoxin conditions. Although a dilutional effect on hormone levels is evident during ECMO, the renin aldosterone system is still able to respond to shock, and results in increased plasma sodium levels.

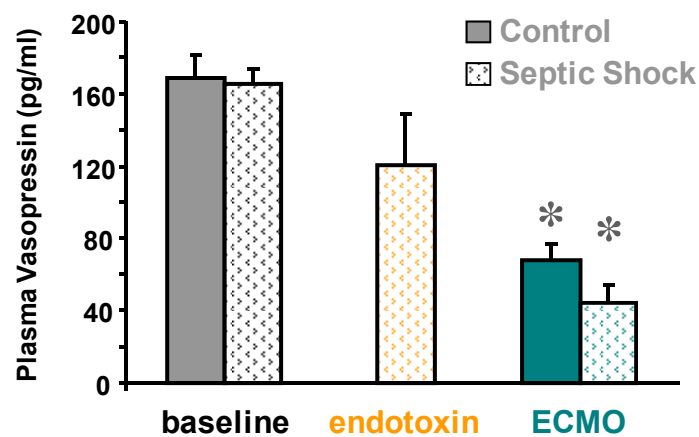


Figure 6. Effects of ECMO on circulating vasopressin levels in control and endotoxemic shock conditions. In both control and endotoxemic animals, VP levels decreased dramatically with ECMO. Although the ECMO circuit is primed with donor whole blood averaging 200 pg/ml of vasopressin, circulating levels still drop. (* = different from baseline, $p < 0.05$). This dilutional effect is seen with cortisol, ACTH, and dopamine as well (data not shown).

Results indicate that while ECMO may provide cardio-respiratory support during endotoxemic shock, disruption of normal relationships in renin aldosterone regulation of sodium balance and blood pressure may occur. Plasma renin activity (PRA) increased appropriately in response to endotoxin-induced shock (Figure 7), however increased PRA was not maintained during ECMO despite persistent hypotension. Overall changes in aldosterone (ALDO) did not occur with ECMO either in control or endotoxemic shock (Figure 7)

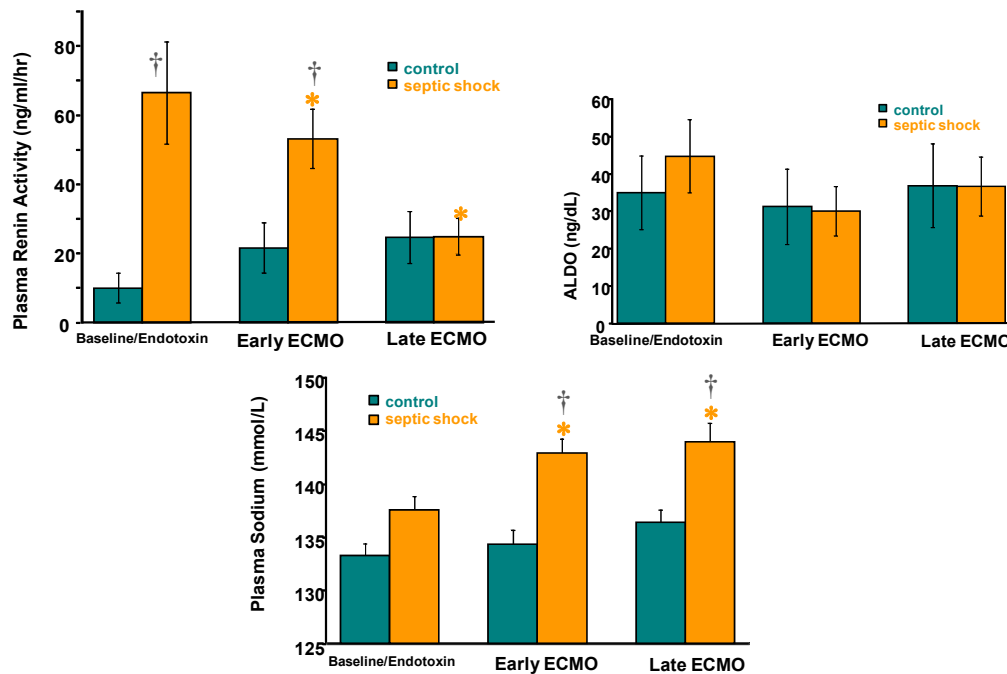


Figure 7. The dilutional effect of the ECMO circuit was not seen with all other electrolytes or hormones. ECMO did not significantly change PRA in control animals. PRA increased appropriately during endotoxic shock but was not maintained during ECMO. ALDO remained constant during ECMO in control and endotoxic shock. While plasma sodium concentrations remained unchanged in control piglets, they increased among endotoxic shock piglets while on ECMO. (* = different from baseline, p<0.05; † = different from control, p<0.05)

Hypothesis B: To compare ECMO delivery effectiveness of blood substitutes versus donor whole blood, on redistribution of perfusion to vital organs and tissue preservation in the face of endotoxin-induced septic shock

One of the concerns about using ECMO is the need to use a relatively large volume of donor blood to prime the ECMO circuit in addition to issues related to exposure to donor blood and risks of viral infections, transfusion reactions, and possible clot embolism (Khoshbin et al, 2005; Spahn and Kocian, 2005). An alternative to the use of donor blood is the use of a blood substitute such as hemoglobin based oxygen-carrying solution (HBOC). A report (York et al, 2002) of a direct comparison of HBOC versus donor blood in healthy animals had shown that the blood substitute may be an effective alternative to using blood for ECMO circuit priming with regards to managing blood gases and pH. However, it is unclear whether this will also suffice when used in a state such as vasodilatory septic shock.

In the initial proposal, we had wanted to examine some of the side effects of the use of blood substitutes such as hemodilution and methemoglobinemia, and whether such conditions during septic shock, when the body is already compromised and struggling to maintain vital organ perfusion, can be tolerated. However, we were unable to obtain a source of artificial

oxygen carrier (AOC) as vendors of such products had gone into bankruptcy and so AOCs were no longer on the market. Thus we had to drop this part of the project. This part of the project was instead replaced by a more in depth look at the effect of ECMO on cardiovascular regulating hormones and the outcomes of shifts in microcirculatory flows as described above.

Beyond the simple dilutional effect of the volume of the ECMO circuit, ECMO seemed to affect the regulation of hormone release to physiological signals (fig 8). The relationship between right atrial pressure and plasma vasopressin levels, for example, was not present during ECMO. Vasopressin plays a vital role in regulating mean arterial pressure (MAP) and regional blood flow in hypotensive disorders, but whether endogenous VP levels can be sustained during ECMO is unclear. In 11 anesthetized, cardiac catheterized piglets were put on veno-arterial ECMO either during control or endotoxin-induced septic shock states. ECMO blood flow was delivered to maintain MAP at baseline levels. Plasma VP (pVP) was compared before and after stabilization on ECMO for 2 hours. ECMO caused pVP to drop by 30% ($p < 0.01$) in both control and septic shock conditions. This drop may be due to the ECMO circuit adding to total circulating volume without additional release of VP. To test whether right atrial pressure (RAP) influence on VP release may be disrupted during ECMO due to partial cardiac bypass of blood flow, the relationship between pVP and hemodynamics during control was examined with stepwise regression. Pre-ECMO, pVP negatively correlated with RAP (Figure 8) ($r = -0.69$, $p < 0.01$), but not MAP. In contrast, during ECMO, this pVP relationship with RAP was lost (Figure 8), but a strong positive correlation ($r = 0.72$, $p < 0.05$) between pVP and MAP became evident (Figure 9).

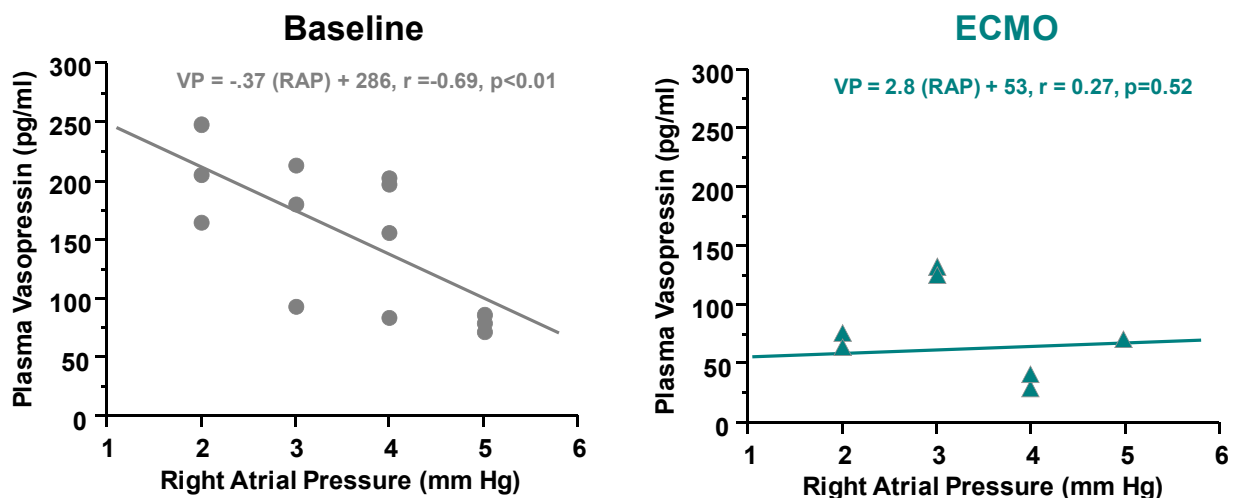


Figure 8. ECMO alters the relationship between VP and right atrial pressure.

Multiple regression stepwise analyses revealed that of all hemodynamic measurements taken, circulating vasopressin levels were most strongly predicted by right atrial pressure. At pre-ECMO baseline, VP negatively correlated with right atrial pressure. However, once put on the ECMO circuit the relationship between vasopressin levels and right atrial pressure was no longer evident, indicating a disruption of low pressure baroreceptor stimulation of vasopressin release.

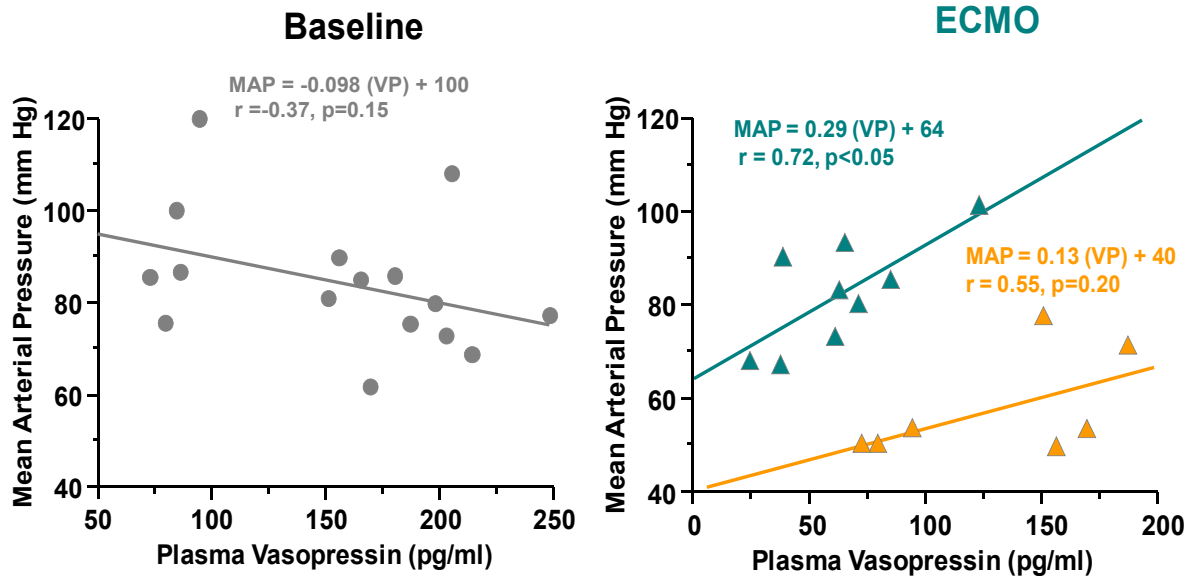


Figure.9. Relationship between circulating vasopressin and mean arterial pressure is unmasked with ECMO. Under normal physiological conditions, a direct correlation between plasma vasopressin levels and blood pressure is difficult to detect. However once on ECMO, in both control and endotoxic animals, a direct relationship between plasma vasopressin and MAP was revealed, indicating that vasopressin still functions as a pressor agent during ECMO.

Results indicate that the partial cardiac bypass and reduction of flow through low pressure systems in the heart may cause alterations in signals by baroreceptor mediation of endogenous vasopressin release. A drop in systemic vasopressin levels upon initiation of ECMO may reflect that endogenous vasopressin release does not keep up with the increased total circulating volume and/or breakdown of the hormone caused by the addition of the ECMO circuit. Hence, despite maintenance of hemodynamic stability, changes in endocrine regulation of cardiovascular and fluid balance appears to occur with ECMO and should be monitored to reduce morbidity outcomes.

Because vasopressin plays a beneficial role in the response to endotoxic shock by redistributing blood flow to vital organs, maintaining blood oxygenation, and preventing renal shutdown, altered vasopressin regulation needs to be carefully monitored. If vasopressin regulation of regional blood flow distribution and fluid balance is disrupted by ECMO, it is not surprising that that edema and other fluid imbalances associated with the use of ECMO will occur. Thus, to reduce morbidity outcomes related to the use of ECMO, the drop in endogenous vasopressin and other fluid and electrolyte hormones during ECMO should perhaps be prevented with exogenous hormone replacement therapy.

We also examined the renin-aldosterone-sodium relationship during ECMO to determine whether ECMO disrupted normal relationships in endocrine regulation of plasma sodium. Plasma sodium concentrations increased after the initial plasma PRA (Figure 7) but a relationship between sodium levels and PRA was not evident (Figure 10) in either control or endotoxic shock state regardless of whether on ECMO or not. This would indicate that blood

pressure was a dominant driver of PRA changes and not sodium levels. The relationship between PRA and ALDO remained intact with ECMO although this relationship is blunted by endotoxemic shock exposure (Figure 11).

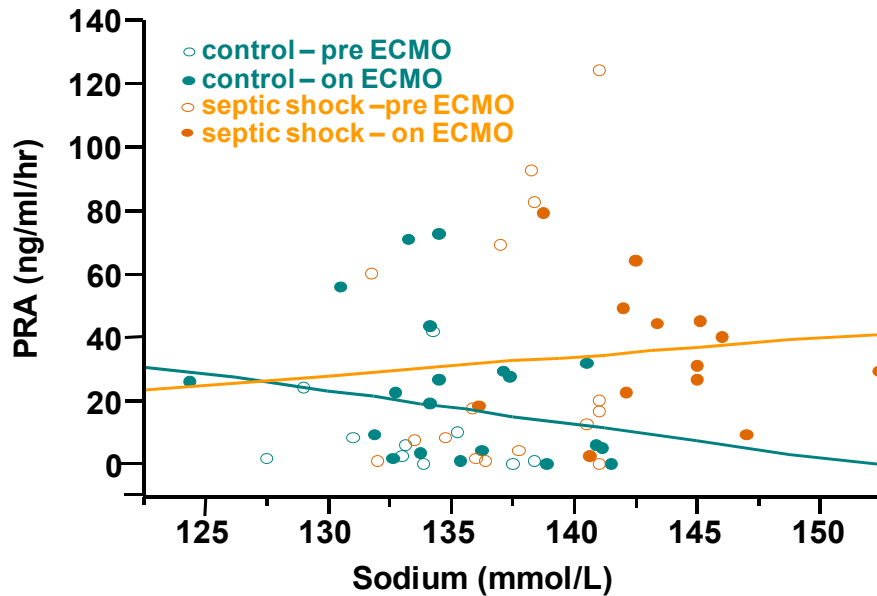


Figure 10. Relationship between PRA and plasma sodium. A correlation between PRA and sodium was not apparent.

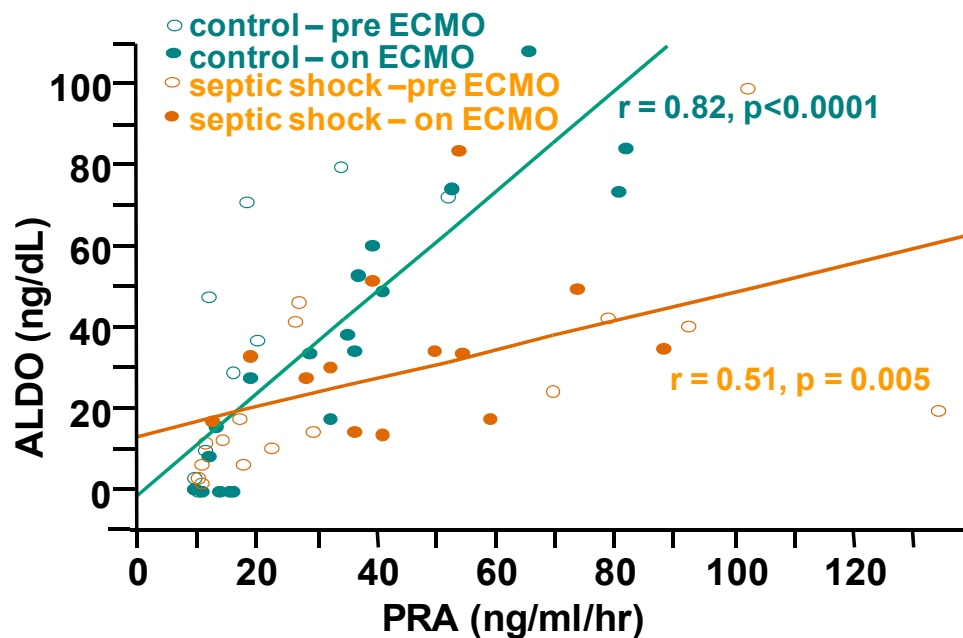


Figure 11. ALDO PRA relationship remains intact in ECMO. ALDO was positively correlated with PRA in both control and endotoxemic shock piglets but that relationship was less sensitive in endotoxemic shock.

Significant changes in ALDO did not occur with ECMO either in control or endotoxemic shock (Figure 7), but control animals exhibited a negative relationship between plasma sodium and ALDO that was not seen with endotoxin exposure (Figure 12).

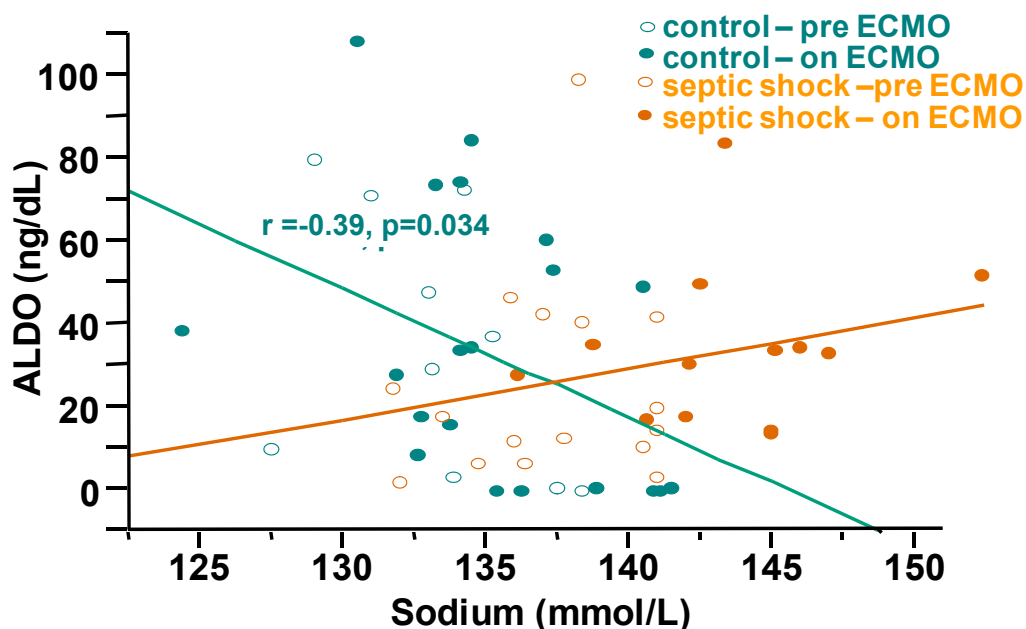


Figure 12. ALDO relationship with plasma sodium. ECMO did not interfere with the negative correlation between ALDO plasma sodium in control pigs but this correlation disappeared in the endotoxemic shock state.

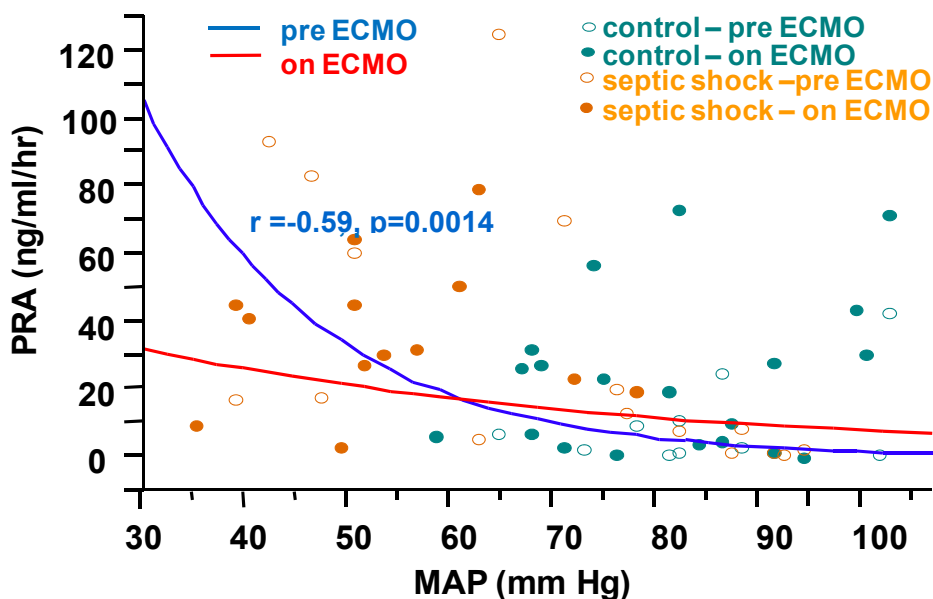


Figure 13. Relationship between PRA and MAP. Prior to ECMO (blue line), PRA increased with decreasing MAP. However that relationship is attenuated with ECMO.

The attenuation of a PRA response to changes in MAP can be seen in Figure 13 where before ECMO there is a negative correlation (blue line) between PRA and MAP in both control and endotoxic animals but during ECMO this relationship is blunted (red line). This may coincide with a change in renal blood flow with ECMO or decreased converting enzyme activity with bypass of blood away from the lungs.

Thus, sodium regulation by ALDO remains intact during ECMO and PRA is attenuated during ECMO in endotoxic shock. Results suggest that ECMO-induced changes in PRA and ALDO regulation should be considered in reducing morbidity outcomes due to altered sodium regulation with the use of ECMO to treat endotoxic shock.

Hypothesis C : To evaluate whether ECMO prevents multi-system organ failure in septic shock, by examining organ function of the lungs and the kidneys, the organs most likely to fail in sepsis.

We evaluated pulmonary function and the resolution of endotoxin-induced persistent pulmonary hypertension as well as renal function, because it is the shutdown of the kidneys and dysfunction of the lungs in achieving proper gas exchange, that lead to the downward spiral of multi-system organ failure and tissue morbidity beyond the immediate reversal of vasodilatory hypotension.

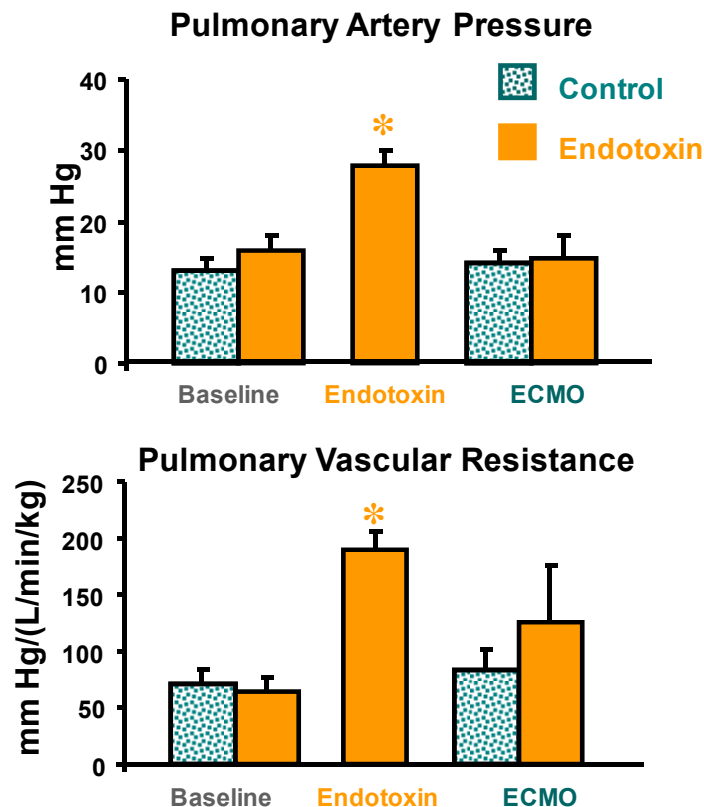


Figure 14. ECMO effects on pulmonary arterial pressure and pulmonary vascular resistance. The pulmonary hypertension induced by endotoxin was reversed with ECMO (* = different from baseline, $p < 0.05$)

Indices of lung function and tissue oxygenation:

Severe pulmonary hypertension caused by endotoxin was reversed with ECMO. Results show that ECMO is able to maintain blood flow to vital organs and reverse pulmonary hypertension and hypoxemia during endotoxic shock.

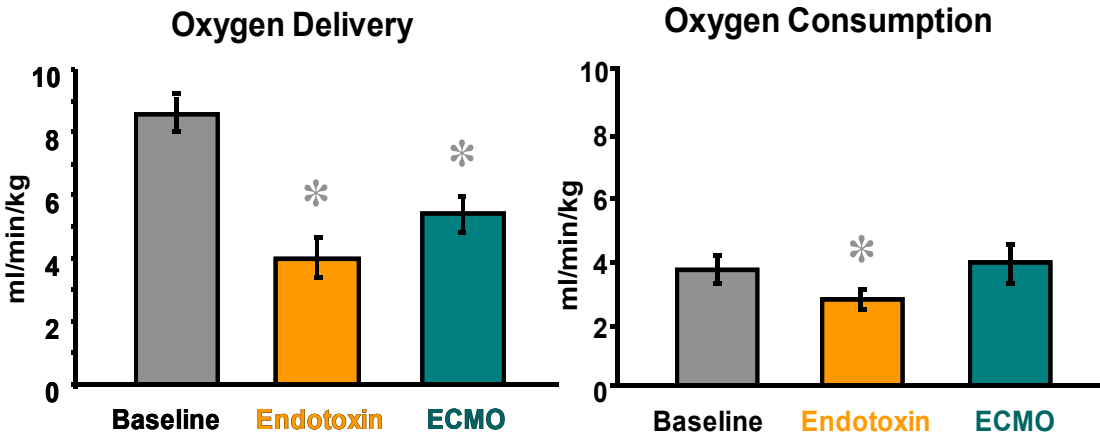


Figure 15. Brain tissue metabolism during baseline, endotoxic shock, and ECMO. During endotoxic shock, oxygen delivery dramatically decreased in association with the hypotension. ECMO treatment did not fully compensate for the decrease in oxygen delivery. However, oxygen consumption was restored with ECMO. (* = different from baseline, $p < 0.05$)

Renal function evaluation:

Based on the dilutional effect of ECMO on circulating hormone levels, we hypothesized that ECMO will not restore urine output in endotoxic shock despite cardiac stabilization and maintenance of blood flow to the kidneys, as ECMO simultaneously reduces endogenous vasopressin levels which are needed to modulate local perfusion pressure and renal filtration. Results indicate that ECMO interferes with the autoregulation ability of the kidneys to provide adequate pressure to restore filtration and urine flow in endotoxic shock.

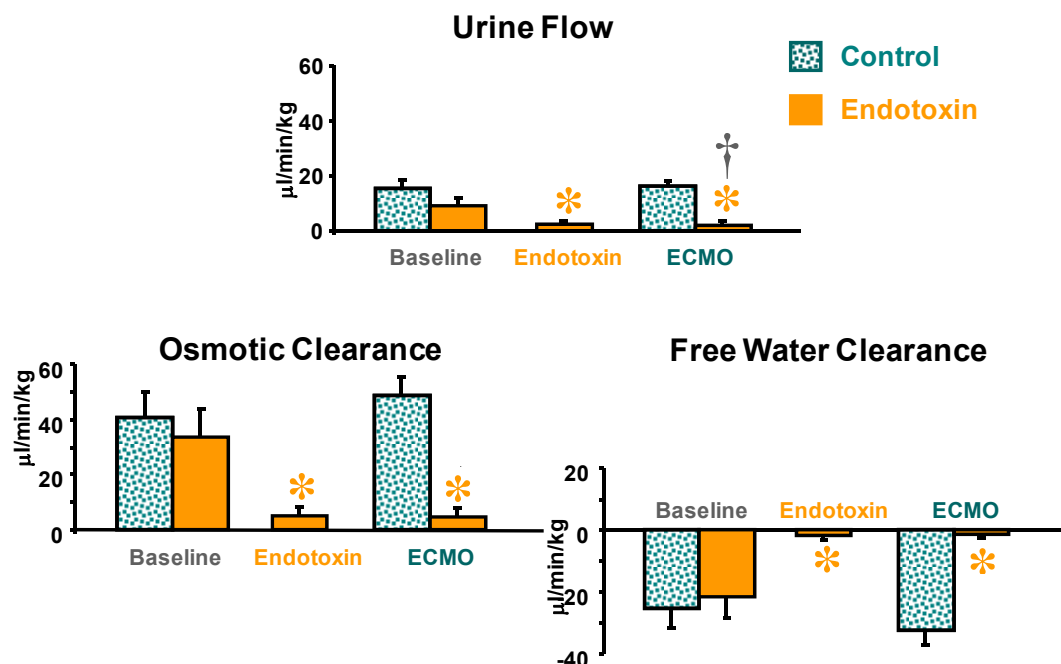


Figure 16. ECMO effects on urine output and free water and osmotic clearances. ECMO does not restore decreased urine flow associated with endotoxin-induced hypotension. (* = different from baseline, $p < 0.05$; † = different from control, $p < 0.05$))

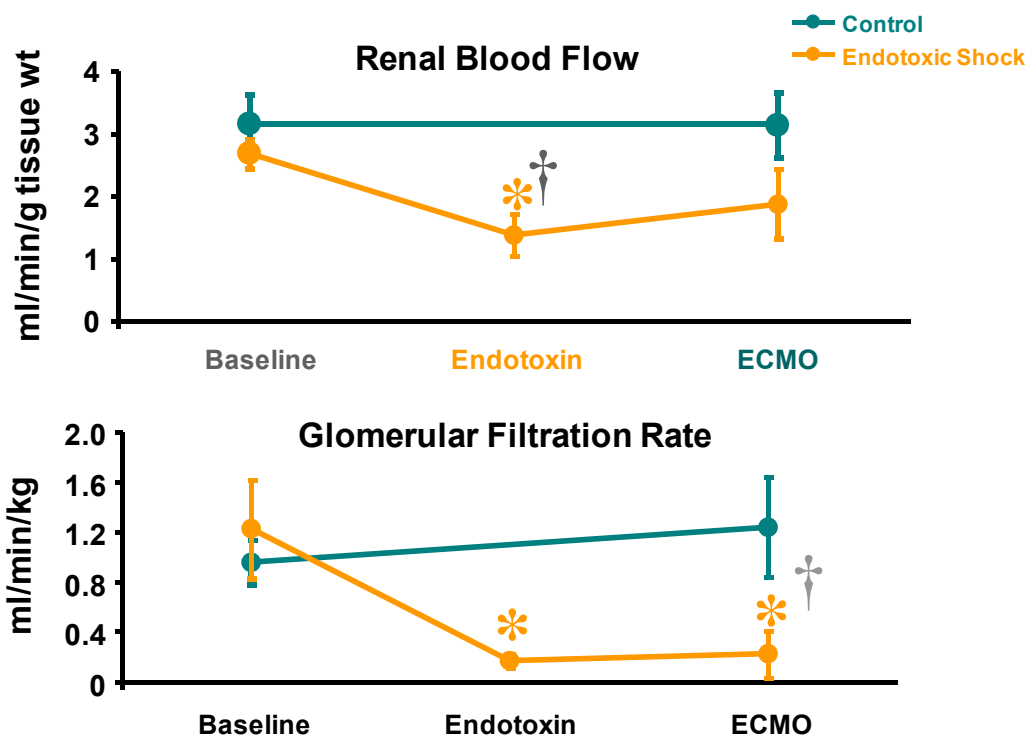


Figure 17. ECMO effects on renal hemodynamics. ECMO did not alter renal hemodynamics in control animals. ECMO was not able to return renal blood flow or glomerular filtration to pre-endotoxin levels. (* = different from baseline, $p < 0.05$; † = different from control, $p < 0.05$)

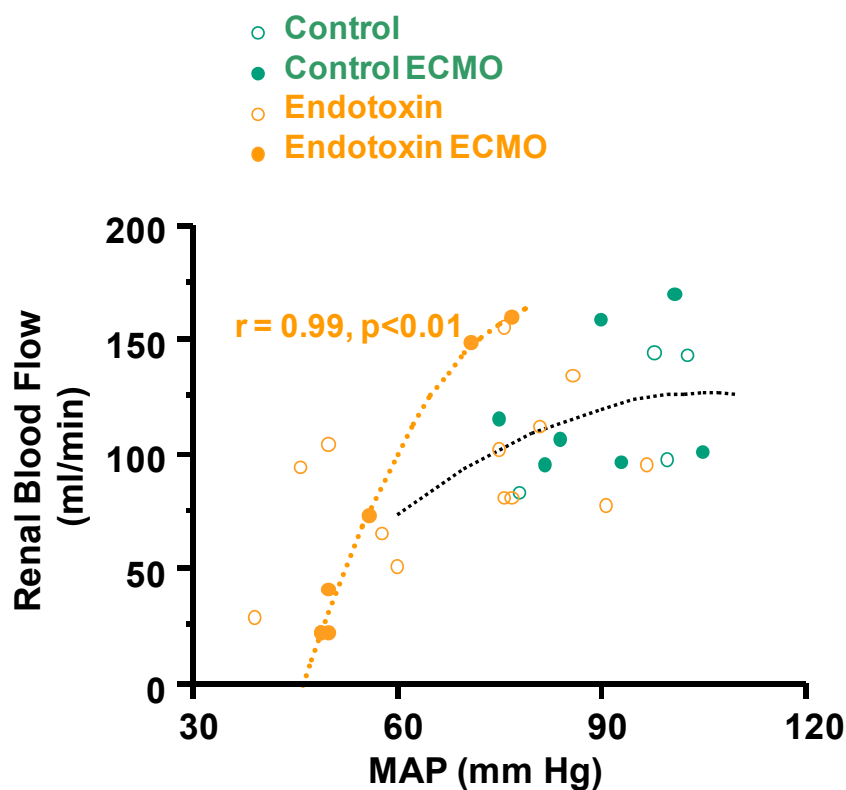


Figure 18. ECMO effects on renal autoregulation. ECMO did not alter renal autoregulation in control animals where renal blood flow remained constant despite differences in MAP. Endotoxic shock caused MAP to drop and fall below the autoregulatory range for renal blood flow. ECMO was not able to restore autoregulation in endotoxic animals and renal blood flow strongly correlated with blood pressure during ECMO in endotoxic shock.

Results indicate that ECMO cannot restore renal function and provide adequate blood flow to the kidneys to restore the drop in renal filtration induced by endotoxic shock. We have previously shown that high vasopressin levels are needed to reverse the low urine output. These current results demonstrate that the simple maintenance of renal blood flow with ECMO at a pressure compatible with auto regulation is not sufficient to restore glomerular filtration. This supports the hypothesis that vasopressin restores urine flow in endotoxic shock by selective vasoconstriction of the renal efferent arterioles to increase filtration pressure.

Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.

a. Develop simulation software and curriculum in conjunction with the infant patient simulator to serve as training adjuncts to animal and wet-lab training.

a.1. Hanuola ECMO Training Course

The Hanuola Center has completed the *Hanuola ECMO Training Course*; a comprehensive, traditional classroom-based ECMO training course for physicians, nurses, respiratory therapists, perfusionists or other health care professionals interested in understanding the concepts of extracorporeal membrane oxygenation. To provide an easily accessible web-based platform to improve pediatric care, the course has been converted to an online format which is available on the Center's training website. Competency learning modules have been developed to maintain ECMO competency for nurses, respiratory therapists and physicians who have already completed the ECMO training course. On 11 and 12 May 2010, an ECMO training course was held using the web-based curriculum and high fidelity manikin simulation. And again on 26 and 27 July 2010, a perfusion competency course using the same format was completed.

a.2. Critical Care Curriculum for Austere Environments

The Center has completed the *Pediatric Critical Care Curriculum for Austere Environments* that integrates manikin-based simulation. This curriculum provides as an online resource for multiple levels of health care providers without specific specialty training in the care of critically ill pediatric patients. This can be accessed through <http://www.hanuola.com>.

b. Evaluate the simulation curriculum.

b.1. Assessment and Intervention for Pediatric Patients in Emergency Situations

To evaluate the simulation curriculum, the Center developed the *Assessment and Intervention for Pediatric Patients in Emergency Situations* simulation-based (manikin) training curriculum. Topics covered include pediatric airway anatomy and physiology, recognition of the pediatric patient in respiratory distress and respiratory failure, and shock. Neurologic emergencies and treatment options in pediatric patients are also discussed.

A total of 25 medical professionals were recruited to evaluate the manikin simulation curriculum, all of which have completed the online web-based didactic training session. 20 of which have completed the manikin portion of the study. Data from 2 participants have been excluded because of missing data points. The other 18 datasets have been analyzed in SPSS; the learner satisfaction survey and curriculum evaluation was completed by 17 participants.

Results from the manikin simulation study demonstrated that Manikin-Based Simulation Training can be used effectively to improve advanced pediatric care skills acquisition, with statistical improvement between sessions ($p < .05$). There was no discernible improvement between Session 2 and Session 3. This is similar to the results reported by DeVita et al., with

the greatest improvements between the first and second training session. This implies that only two training sessions may be necessary. However, with respect to manikin survival, Session 3 (89% with passing score) was necessary for the group to have an overall passing score $\geq 80\%$, as compared to lower passing rates in Session 1 (56%) and Session 2 (78%).

The number of repetitive training scenarios per a single training session is an important issue. Training time is limited by both competing curricula and regulations for student training time (e.g., 80 hour work week for resident physicians). This limits the amount of time for any type of training. If only one or two practice sessions are necessary, eliminating a third or fourth session will save time for trainees and be more cost effective for the institution. However, it is unknown how many sessions should be accomplished once a plateau in training outcomes is reached for a given training session. How repetition impacts skills retention over short and long-term time periods and satisfaction of the learners are important issues that remain largely unanswered. This could be area to evaluate with future research. .

See Attachment B.1. for a more detailed manuscript of the study.

b.2. ECMOjo scenario-based curriculum evaluation

Validation of ECMOjo has been completed at various ECMO Training Centers across the United States. Centers include: Rady Children's Hospital, San Diego, Children's National Medical Center, University of Pittsburgh Medical Center, Wilford Hall Medical Center, Arkansas Children's Hospital, Children's Healthcare of Atlanta, University of Iowa, Mayo Clinic, Lutheran General, and Children's Hospital of Philadelphia. A total of 51 medical professionals were enrolled to participate in an ECMO skills acquisition study. Subjects were randomized into two groups, one group doing conventional classroom learning and the other training on ECMOjo over the same period. Both groups were assessed using three wet-lab scenarios after their training, with wet-lab results compared between groups.

Results for the ECMO skills acquisition study indicate that ECMOjo is *equivalent* in training when compared to standard didactic classroom learning. No differences have been observed between groups trained with ECMOjo versus participants trained in the classroom. Also, ECMOjo has been shown to train both novices and experts equally.

We believe ECMOjo is a valuable addition to current state-of-the-art ECMO training practices. ECMOjo is a computer-based simulation model that can provide important cognitive skills training and practice that is not possible in a classroom setting. With equality between ECMOjo and didactic training, it can be utilized instead of didactic training prior to the wet-lab experience. One of the postulated benefits of ECMOjo that can be explored with future research is to practice and train more difficult clinical and pump scenarios for ECMO providers. The simulator makes this possible. This would be more difficult to teach in a classroom setting. Future research could help to define the benefit of ECMOjo for more advanced training scenarios.

See Attachment C.1. for a more detailed manuscript of the study.

Key Research Accomplishments

Task 1. To establish a new Hawaii-Pacific Rim extracorporeal life support (ECLS) Center, which provides advanced levels of care to Pediatric patients with life-threatening cardiorespiratory failure; to evaluate the Center's effectiveness in attaining clinical results that meet national ECLS benchmarks.

- Training manual developed for Hanuola ECMO Center. Hardcopy and electronic versions are available.
- Website has been developed at <http://www.hanuola.com>. Information includes
 - Hanuola Center information
 - Reference center for parents
 - Grant information
 - Access to ECMO and PCC curriculum
 - Pediatric Critical Care Curriculum for Austere Environments
- Parent Teaching Materials have been developed. Hardcopy and electronic versions are available.
- ECMO Training Course—course curriculum has been developed and is ongoing to provide review and maintenance of skills.
- Hanuola ECMO Transport system has been acquired with FAA certification

Task 2. To conduct basic science research to advance scientific knowledge in ECLS.

- Animal model for ECMO treatment of bacterial endotoxin-induced catecholamine-resistant vasodilatory septic shock has been developed.
- Using a piglet model of vasodilatory endotoxin-induced septic shock, we have characterized the cardiovascular and endocrine responses to ECMO
- Clinical guidelines recommended for use of ECMO based on our results:
 - ECMO can be used to help provide cardiorespiratory support during septic shock as it is able to maintain blood flow to vital organs and reverse pulmonary hypertension and hypoxemia during endotoxic shock.
 - Results demonstrate the effectiveness of ECMO in preserving brain perfusion. In non-endotoxic shock conditions, care must be taken to avoid over-perfusion of the brain with ECMO. The ECMO flow delivery needs to be adjusted according to oxygen saturation rather than trying to maintain a “normal” mean arterial pressure, especially during endotoxic shock where excessive vasodilatation occurs. Blood flow is maintained by ECMO despite comparatively low blood pressures.
 - ECMO causes a dilutional effect on endogenous vasopressin and other hormone levels in both control and endotoxic shock conditions, and hormonal replacement therapy should be considered
 - In contrast to the ECMO induced decrease seen with other hormones, PRA and aldosterone were still able to respond to endotoxic shock and elevate sodium levels. Resultant fluid retention should be carefully monitored.

- ECMO-induced changes in vasopressin regulation and low pressure system signaling for vasopressin release should be considered in reducing morbidity outcomes with the use of ECMO to treat endotoxic shock.
- ECMO is able to maintain hemodynamic stability, however changes in endocrine regulation of cardiovascular and fluid balance appears to occur and should be monitored with prolonged ECMO treatment to reduce morbidity outcomes. Such changes in endocrine function should also be considered in weaning a patient off of ECMO.

Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.

- Web platform has been created and course content has been loaded
- The following website contains the online learning portion and related quizzes
<http://www.tri.jabsom.hawaii.edu/manikinstudy/login.html>
- The following website contains the simulation portion and related quizzes for the study
http://simtiki.simmedical.com/apps/courses/courseview.asp?course_id=6277
- Evaluation of the simulation curriculum, *Assessment and Intervention for Pediatric Patients in Emergency Situations*, has been completed and manuscript drafted.

Task 4. To develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.

- The development of ECMOjo, a simulator and trainer for extracorporeal membrane oxygenation, has been completed.
- Validation study has been completed and manuscript drafted.
- Project software has been updated at SourceForge.net and is available as Open Source for ECMO practitioners worldwide.
<http://ecmojo.sourceforge.net>

Reportable Outcomes

- Abstracts, Presentations, Publications:
 - Dr. Mark Ogino presented the program at the following:
 - *The 17th Annual ELSO Conference*, September 15-17, 2006, Atlanta **Georgia**
 - *The 24th Annual Children's National Medical Center Symposium on ECMO & Advanced Therapies for Respiratory Failure*, February 25 – March 1, 2007, Keystone, Colorado
 - *Pediatric Academic Societies & Asian Society for Pediatric Research Joint Meeting*, May 2-6, 2008, Honolulu, HI
 - *The 18th Annual ELSO Conference*, September 21-24, 2007, San Diego, California
 - *Center for Integration of Medicine and Innovation Technology (CIMIT): Innovation Congress Conference*, November 13 – 14, 2007, Boston, Massachusetts
 - *Overview of the UPMC IMITs ECMO Initiative with The University of Hawaii*: Included in IMITs presentation given by Dr. Juan Carlos Payana, IMITs Chief Medical Officer, at the Center for Integration of Medicine and Innovation Technology (CIMIT): Innovation Congress Conference, November 13 – 14, 2007, Boston, Massachusetts
 - *The 26th Annual Children's National Medical Center Symposium on ECMO & Advanced Therapies for Respiratory Failure*, Keystone CO. Feb 2010.
 - *Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training*, L. Y. Tanaka, M. T. Ogino, C. Aschwanden, K. Costales, L. Burgess, Society for Simulation in Healthcare, 2009, Poster Abstract
 - Tanaka LY, Aschwanden C, Burgess L, Ogino MT. Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training. *International Medical Simulation in Healthcare*, Phoenix, AZ. Jan 2010. 5
 - Tabak BD, Tanaka LY, Mahnke CB, Elliott CL, Costales KG, Ogino MT. Echo for ECMO: Guiding Avalon Catheter Placement for VV ECMO. *ECMO and the Advanced Therapies for Respiratory Failure*, Keystone, CO. Feb 2010. (platform presentation)
 - Costales KC, Tanaka TY, Kilcommons MM, Takenaka WS, Sommer-Candelario SA, Ogino MT. Santa's Got a Brand New Sled. *ECMO and the Advanced Therapies for Respiratory Failure*, Keystone, CO. Feb 2010. (platform presentation) Appendix A.1.
 - Costales KC, Kilcommons MM, Takenaka WS, Ogino MT. ECMO Transport Across the Pacific: A Case Report. Poster presentation. *ECMO and the Advanced Therapies for Respiratory Failure*, Keystone, CO. Feb 2010. Appendix A.2
 - Tabak BD, Tanaka LY, Mannke CB, Elliott CL, Costales KC, Ogino MT. Echocardiographic Evaluation of the Avalon Elite Bi-caval Dual Lumen Catheter in Neonatal and Pediatric VV ECMO. *ECMO and the Advanced Therapies for Respiratory Failure*, Keystone, CO. Feb 2010.

- L. Y. Tanaka, M. T. Ogino, C. Aschwanden, K. G. Costales and L. Burgess. Computer-Based Simulation Application for Extracorporeal Membrane Oxygenation (ECMO) Skills Training Poster presentation. 10th Annual International Meeting on Simulation in Healthcare (IMSH), Phoenix, Arizona, January 23-27, 2010
- Uyehara CFT, Batts SG, Kinnison MW, McEntire SP, Sato AK, Ichimura WM, Hashiro GM, and Hernandez CA. Vasopressin Regulation During Extracorporeal Membrane Oxygenation (ECMO) in a Pig Model of Septic Shock. FASEB J. 23: 605.1, 2009.
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- Uyehara CFT, Sato AK, Hernandez CA, Ichimura WM, Batts S, Mu TS, Andaya JM. Extracorporeal Membrane Oxygenation (ECMO) Does Not Restore Renal Autoregulation in Endotoxin-Induced Acute Renal Failure. FASEB J. 24: 793.11, 2010.
- Uyehara CFT, Sato AK, Murata, L, Hernandez CA, Wong TJ, Ichimura WM Vasopressin Pituitary Stores Acutely Released in Vasodilatory and Hypovolemic Shock Are Not Immediately Restored With Prolonged Hypotension. To be presented at Experimental Biology 2011, Washington, D.C. April 2011.
- Cardiovascular Hormonal Responses and Microcirculatory Flow During ECMO Treatment in a Piglet Model of Endotoxic Shock. Catherine F T Uyehara, Sherreen G Batts, Thornton S Mu, Sarah L Lentz-Kapua, Martin W Kinnison, Aileen K Sato, Wayne M Ichimura, and Claudia A Hernandez. Presented at The Department of Defense Peer Reviewed Medical Research Program Military Health Research Forum, Kansas City Missouri, August 2009. (Hosted by The U.S. Army Medical Research and Materiel Command.)
- The animal study task has been successfully used to provide research opportunities for military Graduate Medical Education trainees, and to develop research interests of residents and staff of Tripler Army Medical Center's Department of Surgery. Results were presented by military GME trainees at the following:
 - Podium presentation at COMPRA, Bastrop, Texas November 2008
 - Poster presentation at PAS, Baltimore, Maryland April 2009
 - Podium presentation at Presentation: Military Health Research Forum 2009
 - Podium presentation at 2009 Annual Gary P. Wratten Surgical Symposium, Tacoma,
 - Podium presentation at AAP national convention Perinatal Section Washington, D.C. Platform session October 2009
 - Podium presentation at COMPRA, Bastrop, Texas November 2009
 - Podium presentation at 11th Annual James W. Bass Research Symposium, 20 May 2010, Tripler AMC, HI.
 - Podium presentation at 12th Annual James W. Bass Research Symposium, 19 May 2010, Tripler AMC, HI.
 - Podium presentation at 29th Annual Conference of Military Perinatal Research, 6 Nov 2010, Austin, TX.

- Podium presentation at 77th Perinatal & Developmental Medicine Symposium, 13 Nov 2010, Marco Island, FL.
 - Podium presentation at 29th Annual Conference on Military Perinatal Research (COMPRA) Austin, TX Nov 2010
 - Podium presentation at 45th Annual Uniformed Services Pediatric Seminar, Mar 2011, Washington, DC
 - Poster presentation at 2011 Pediatric Academic Societies, May 2011, Denver, CO
 - Poster presentation at Uniformed Services Pediatric Seminar (USPS) March 2011
 - ECMO Physician Credentialing
 - All PICU physician staff have been certified.
 - Certification all Pediatric surgeons for Level 2 credentials has been completed.
- Data submitted to ELSO registry
- The animal model for endotoxin-induced septic shock using a pediatric piglet model has been completed and results are currently being analyzed.
- Design, engineering and purchase of the ECMO Transport Sled is complete.
- Review article published in AmSECT Today, Sept/Oct 2010 edition, pg 7.
- Awards
 - Various aspects of this work was presented at Research Competitions by LTCOL Sherreen Batts, MAJ Thornton Mu, and Capt Eldon Palmer. They have won the following:
 - Second place award at the 2009 James W. Bass Research Symposium Resident Competition (LTCOL Batts)
 - Third place award at the 2010 James W. Bass Research Symposium Resident Competition (MAJ Mu)
 - Finalist for Uniformed Services Pediatrics award at the 45th Annual Uniformed Services Pediatric Seminar (MAJ Mu)
 - Semifinalist for the Ogden-Bruton award (top 6 of 40) at the Uniformed Services Pediatric Seminar
- New Grant Awards
 - "Maintaining Tissue Viability After Acute Hemodynamic Stabilization in Models of Shock, Polytrauma and Wound Infection" (#D10_1_AR_J6_925) Catherine Uyehara Principal Investigator \$993,438.80 U.S. Army Medical Research and Materiel Command Core Research Program, FY08 War Supplemental Intramural Research Program
 - "Removal of pro-inflammatory cytokines to reduce lung inflammation in a porcine model of controlled hemorrhage" MAJ Thornton Mu Principal Investigator \$196,000 Department of Defense FY10 Defense Medical Research and Development Program Applied Research and Advanced Technology Development Award

Conclusions

The Hanuola (ECMO) Center has been successfully established at Kapi'olani Medical Center for Women and Children. The following are a summary of accomplishments:

- Policies and procedures with other supporting clinical departments have been integrated into the program.
- ECMO patients are currently being treated and consulted, a total of 21 patents have been on ECMO during the contracting period.
- An ECMO transport system has been certified and is available for use for the Center into the future.
- Both an ECLS competency training curriculum and animal training platform have been developed and available for use into the future.
- Animal model for ECMO treatment of bacterial endotoxin-induced catecholamine-resistant vasodilatory septic shock has been developed.
- Web platform has been created for the *Hanuola ECMO Training Course*; a comprehensive, traditional classroom-based ECMO training course for physicians, nurses, respiratory therapists, perfusionists or other health care professionals interested in understanding the concepts of extracorporeal membrane oxygenation. Also, the *Critical Care Curriculum for Austere Environments* course is also available on the website.
- ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data has been developed and made available online for ECMO practitioners worldwide.

The establishment of the Hanuola Center has significantly improved the level of care provided to DOD dependents in the Pacific region and to all children in the State of Hawaii. The Hanuola Center is now providing state-of-the-art critical care support for patients and state-of-the-art educational opportunities to pediatric providers, which is bringing the standard of care for pediatric patients in Hawaii to an equal footing with patients on the U.S. mainland.

Unfortunately, morbidity and mortality associated with septic shock remain high, and thousands of patients die each year from multi-function organ failure as a consequence of sepsis.

Immediate treatment to support ventilation, and maintain sufficient organ perfusion is important in improving clinical outcomes. With the hazardous conditions our deployed soldiers must face, including wound infections in addition to potential exposure to biological and chemical warfare agents, the chances for development of sepsis which may lead to pulmonary and cardiovascular collapse is a reality

Results presented here indicate that ECMO may help reduce morbidity and mortality from endotoxin-induced shock by providing cardio-respiratory support. This study has led to a better understanding of the effects of ECMO on tissue perfusion and cardiovascular hormone regulation in control and endotoxic shock conditions. Since this project was initiated, ECMO is increasingly being used to treat cardiorespiratory failure for a wider range of indications in the pediatric and adult populations.

Recommendations for critical care guidelines for the use of ECMO are:

- ECMO pump flows should be adjusted according to oxygen saturation values rather than trying to maintain a control level blood pressure as trying to achieve higher blood pressures may cause over-perfusion of delicate brain tissues.
- Cardiovascular hormone replacement therapy should be considered to counteract the dilutional effects of ECMO circuit on critical cardiovascular hormones to maintain normal fluid and electrolyte regulation if a patient will be kept on ECMO treatment for prolonged periods.

Septic shock is a high-risk disease of infection seen in all military hospitals. Susceptibility of battlefield wounds to infections and possibilities of soldier exposure to biological warfare agents makes the treatment of septic shock a significant “military relevant disease management” concern. Guidelines for perfusion parameters and hormone replacement therapy provided by this study help clarify the role for ECMO in the treatment of septic shock in military clinical practice.

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Appendices

- A. Task 1.a. Establish ECLS Center at Kapi'olani Medical Center for Women and Children using well-established clinical and referral guidelines, and training curricula**
 - Appendix A.1. ELSO Results, Hanuola Center
 - Appendix A.2. ECLS Registry Report for Hanuola Center

- B. Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.**
 - Appendix B.1. Evaluation of Manikin-Based Simulation Training for the ECLS Training Curriculum - *Manuscript*

- C. Task 4. Develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.**
 - Appendix C.1. Validation of ECMOjo, a Computer Simulator for Extracorporeal Membrane Oxygenation (ECMO) – *Manuscript*

Appendix A.1

Hanuola - ECMO Program of Hawaii (176)

<i>Unique ID</i>	<i>PatID</i>	<i>Run</i>	<i>Birthdate</i>	<i>Age</i>	<i>Date On</i>	<i>Date Off</i>	<i>D/C Alive</i>
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Pulmonary

Neonatal

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1762009005	42413	1	9/2/2009 14:24	5 Days	9/7/2009 7:21	9/11/2009 18:21	True
1762009006	42414	1	10/3/2009 9:44	1 Days	10/4/2009 9:26	10/11/2009 13:07	True
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1762010004	45631	1	11/12/2010 20:06	5 Days	11/17/2010 11:54	11/20/2010 12:17	False

Pediatric

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Adult

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Cardiac

Neonatal

1762008003	39181	1	7/9/2008 16:20	10 Days	7/19/2008 11:59	7/23/2008 10:00	True
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Pediatric

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1762009007	42415	1	7/27/2009 0:00	3 Months	10/12/2009 9:16	10/28/2009 8:30	True

ECPR

Pediatric

1762009008	42416	1	11/24/2001 0:00	7 Years	10/27/2009 17:08	10/29/2009 14:59	False
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Tuesday, December 14, 2010

Appendix A.2

ECLS Registry Report

Center Specific Summary

January, 2011

Hanuola - ECMO Program of Hawaii (176)



Extracorporeal Life Support Organization
2800 Plymouth Road
Building 300, Room 303
Ann Arbor, MI 48109

Overall Outcomes

	<i>Total Patients</i>	<i>Survived ECLS</i>		<i>Survived to DC or Transfer</i>	
Neonatal					
Respiratory	11	9	82%	8	73%
Cardiac	1	1	100%	1	100%
Pediatric					
Respiratory	4	3	75%	1	25%
Cardiac	3	3	100%	2	67%
ECPR	1	0	0%	0	0%
Adult					
Respiratory	1	1	100%	1	100%
Total	21	17	81%	13	62%

Neonatal Respiratory (0-30 days)

Neonatal Respiratory Runs by Year

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2007	2	2	110	123	1	50%
2008	2	4	159	295	2	100%
2009	4	8	91	172	3	75%
2010	3	11	66	79	2	67%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Neonatal Respiratory Runs by Diagnosis

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
PPHN/PFC	6	71	107	5	83%
Other	5	135	295	3	60%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Neonatal Respiratory Support Mode Details

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VVDL	5	57	79	3	60%
VVDL+V	4	100	172	4	100%
VV-VA	1	123	123	0	0%
VA+V	1	295	295	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Neonatal Respiratory Complications

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Hemorrhagic: Cannulation site bleeding	2	18.2%	2	100%
Hemorrhagic: Surgical site bleeding	1	9.1%	0	0%
Hemorrhagic: Disseminated intravascular coagulation (DIC)	2	18.2%	1	50%
Neurologic: Seizures: clinically determined	2	18.2%	1	50%
Neurologic: CNS hemorrhage by US/CT	3	27.3%	3	100%

Hanuola - ECMO Program of Hawaii (176) Center Specific Summary - January, 2011

Renal: Creatinine > 3.0	1	9.1%	1	100%
Renal: Hemofiltration required	1	9.1%	1	100%
Renal: CAVHD required	2	18.2%	1	50%
Cardiovascular: Inotropes on ECLS	8	72.7%	6	75%
Cardiovascular: Hypertension requiring vasodilators	1	9.1%	0	0%
Metabolic: Glucose < 40	1	9.1%	0	0%
Metabolic: Glucose > 240	1	9.1%	1	100%
Metabolic: Hyperbilirubinemia (> 2 direct or > 15 total)	2	18.2%	2	100%

Pediatric Respiratory (>30 days and < 18 years)

Pediatric Respiratory Runs by Year

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2009	3	3	407	456	1	33%
2010	1	4	645	645	0	0%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Pediatric Respiratory Runs by Diagnosis

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Bacterial pneumonia	1	645	645	0	0%
Other	3	407	456	1	33%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Pediatric Respiratory Support Mode Details

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VVDL+V	2	382	442	1	50%
VV-VA	1	456	456	0	0%
VVDL	1	645	645	0	0%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Pediatric Respiratory Complications

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Mechanical: Oxygenator failure	1	25.0%	1	100%
Mechanical: Clots: other	1	25.0%	0	0%
Mechanical: Air in circuit	1	25.0%	1	100%
Hemorrhagic: Cannulation site bleeding	2	50.0%	1	50%
Hemorrhagic: Surgical site bleeding	2	50.0%	0	0%
Hemorrhagic: Disseminated intravascular coagulation (DIC)	2	50.0%	0	0%
Neurologic: Seizures: clinically determined	1	25.0%	0	0%
Neurologic: CNS hemorrhage by US/CT	1	25.0%	0	0%
Renal: Hemofiltration required	2	50.0%	0	0%
Renal: CAVHD required	3	75.0%	0	0%
Cardiovascular: Inotropes on ECLS	4	100.0%	1	25%
Cardiovascular: Hypertension requiring vasodilators	1	25.0%	0	0%

Adult Respiratory (18 years and over)

Adult Respiratory Runs by Year

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2010	1	1	151	151	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Adult Respiratory Runs by Diagnosis

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Acute resp failure, non-ARDS	1	151	151	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Adult Respiratory Support Mode Details

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VVDL	1	151	151	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Adult Respiratory Complications

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Renal: CAVHD required	1	100.0%	1	100%
Cardiovascular: Inotropes on ECLS	1	100.0%	1	100%
Pulmonary: Pneumothorax requiring treatment	1	100.0%	1	100%
Pulmonary: Pulmonary hemorrhage	1	100.0%	1	100%
Metabolic: Glucose > 240	1	100.0%	1	100%

Cardiac**Cardiac Runs by Year**

Age Group: 0 - 30 days

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2008	1	1	95	95	1	100%

Cardiac Runs by Year

Age Group: 31 days and < 1 year

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2009	1	1	383	383	1	100%

Cardiac Runs by Year

Age Group: 1 year and < 16 years

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2008	1	1	108	108	0	0%
2009	1	2	105	105	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Runs by Diagnosis

Age Group: 0 - 30 days

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Congenital Defect	1	95	95	1	100%

Age Group: 31 days and < 1 year

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Congenital Defect	1	383	383	1	100%

Age Group: 1 year and < 16 years

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Congenital Defect	1	108	108	0	0%
Cardiogenic Shock	1	105	105	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Runs by Surgical type

Age Group: 0 - 30 days

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Other postop, not bridged	1	95	95	1	100%

Age Group: 31 days and < 1 year

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Other postop, not bridged	1	383	383	1	100%

Age Group: 1 year and < 16 years

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Other postop, not bridged	2	106	108	1	50%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Congenital Diagnoses

Age Group:	0 - 30 days	Total Runs	Avg Run Time	Longest Run Time	Survived	% Survived
Other		1	95	95	1	100%

Cardiac Congenital Diagnoses

Age Group:	31 days and < 1 year	Total Runs	Avg Run Time	Longest Run Time	Survived	% Survived
Cyanotic incr. pulm. congestion (TAPVR / PAPVR)		1	383	383	1	100%

Cardiac Congenital Diagnoses

Age Group:	1 year and < 16 years	Total Runs	Avg Run Time	Longest Run Time	Survived	% Survived
Hypoplastic left heart		1	108	108	0	0%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Runs by Procedure

Age Group:	0 - 30 days	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
	Blalock-Taussig, modified	1	95	95	1	100%

Cardiac Runs by Procedure

Age Group:	31 days and < 1 year	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
	Anomalous venous return repair	1	383	383	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Support Mode Details

Age Group: 0 - 30 days

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VA	1	95	95	1	100%

Age Group: 31 days and < 1 year

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VA	1	383	383	1	100%

Age Group: 1 year and < 16 years

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VA+V	1	105	105	1	100%
VA	1	108	108	0	0%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Complications (0-30 days)

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Hemorrhagic: Cannulation site bleeding	1	100.0%	1	100%
Cardiovascular: Hypertension requiring vasodilators	1	100.0%	1	100%

Cardiac Complications (31 days and < 1 year)

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Mechanical: Cannula problems	1	100.0%	1	100%
Hemorrhagic: Disseminated intravascular coagulation (DIC)	1	100.0%	1	100%
Renal: Hemofiltration required	1	100.0%	1	100%
Cardiovascular: Inotropes on ECLS	1	100.0%	1	100%
Cardiovascular: Hypertension requiring vasodilators	1	100.0%	1	100%
Pulmonary: Pulmonary hemorrhage	1	100.0%	1	100%
Infectious: Culture proven infection (see Infections)	1	100.0%	1	100%

Cardiac Complications (1 year and < 16 years)

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Hemorrhagic: Cannulation site bleeding	1	50.0%	0	0%
Renal: CAVHD required	2	100.0%	1	50%
Cardiovascular: Inotropes on ECLS	2	100.0%	1	50%
Cardiovascular: Myocardial stun by echo	1	50.0%	1	100%
Metabolic: Hyperbilirubinemia (> 2 direct or > 15 total)	1	50.0%	0	0%

Appendix B.1

Evaluation of Manikin-Based Simulation Training for the ECLS Training Curriculum

Christoph Aschwanden, PhD

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Abstract

Objective: Study the effect of manikin training on existing ECLS curriculum topics. It is hypothesized that manikin-based simulation training results in better advanced pediatric care skills acquisition and manikin survival than didactic training alone.

Summary Background Data: Manikin based simulations have been mainstays in medical education for many years, with less advanced manikins utilized in certification courses like Basic Life Support (BLS). Simulators are recognized by the Accreditation Council of Graduate Medical Education (ACGME) as a valid method in assessing clinical competency (ACGME Toolbox, 2000). To date, no manikin training has been integrated into the ECLS curriculum.

Methods: A total of 25 medical professionals have been enrolled to participate in a manikin-based simulation training curriculum. The subjects went through an online web-based didactic training as well as a hands-on manikin training.

Results: With $p < .05$ results indicate that the Manikin-Based Simulation Training for the ECLS Training Curriculum can be used effectively to improve advanced pediatric care skills acquisition. A post-training learner survey has shown strong learner satisfaction.

Overview

With the recent introduction of a computerized infant manikin, SimBaby (SimBaby™, Laerdal), the opportunity now exists to improve on the current educational curriculum and apply manikin-based simulation technology to ECLS training. With proper development and evaluation, simulation modules can supplement current training, and potentially replace other parts of the curriculum in the future.

Manikin based simulations have been mainstays in medical education for many years, with less advanced manikins utilized in certification courses like Basic Life Support (BLS). Simulators are recognized by the Accreditation Council of Graduate Medical Education (ACGME) as a valid method in assessing clinical competency (ACGME Toolbox, 2000). The application of advanced computer technology with anatomic, physiologic, and pharmacologic realism has increased the applicability for manikins to provide advanced simulation training in many areas of acute care medicine. For many years, physicians have depended on bedside teaching to impart knowledge to trainees. This concept has become less popular because of concern over patient safety, as well as it being difficult to have a representative patient available for each diagnosis.

The ethical imperative to use simulation in training whenever possible is an important concept, as patients are protected instead of being commodities in training (Ziv et al, 2003). As such, simulation training provides an important and well-recognized bridge between the textbook and the bedside.

Simulation is also important because it has repeatability and can be standardized. In this way, multiple trainees can receive the same educational experience again and again until concepts are learned and performance is optimal, and is less dependent on having highly qualified physician specialists for training learners, as there is no risk to the manikin as there would be to a patient. Finally, simulation is readily available for longitudinal training. It has been shown that learned skills such as cardiopulmonary resuscitation (CPR) can deteriorate as early as 2 weeks after training, both in lay persons and in medical personnel (Wright et al, 1989; Kay et al, 1986), with skills equaling pre-assessment baseline at 6-months for physicians and nurses (Gass and Curry, 1983). Frequent retraining is essential for infrequently performed procedures like CPR, and simulation training provides an opportunity to train and retrain so skills can be maintained.

Manikin simulations will be a significant new enhancement to ECLS training, with a literature search revealing no articles on the use of manikin simulators for ECLS. The animal labs primarily train for pump and circuit management, but there is no good current model to demonstrate and manage patient physiology for ECLS. The physiologic changes in the pre-ECLS state and physiologic changes while under ECLS can be modeled in the manikin, and thus applied to the existing ECLS training curriculum. This follows the ATLS model, where manikins can be used as a valuable learning tool to improve established training curricula. The manikin will assist trainees to recognize, diagnose, and manage these physiologic changes in a simulated, life-like environment, bridging the educational gap between didactics in the textbook/classroom to the bedside.

Materials

The University of Pittsburgh Medical Center and its Winter Institute for Simulation Education and Research (WISER) have extensive experience in curriculum development and integration of simulation technologies into curricula. WISER developed a combined on-line didactic curriculum followed by a manikin-based, simulation training program for ECLS providers to use to augment animal lab training and clinical experience. The training program will allow providers to become more familiar with patient physiology prior to and during an ECLS run and allow them to identify and manage certain physiologic states more readily. Such a training system has not been established in the past and could eventually serve not only the Hawaii ECLS community, but the ECLS community in its entirety.

WISER has designed a curriculum development model that will be used for this part of this project and for other pieces of curriculum development within this project. This curriculum development piece involves a comprehensive 181-step plan from project initiation to final deliverable product. The training curriculum (ECMO Specialist Manual) will be augmented with the manikin as discussed above in the following areas:

1. Cardiorespiratory status in the pre-ECMO state
2. ECMO physiology
3. Cardiac changes during ECMO
4. Management of the neonate on ECMO
5. Management of the pediatric ECMO patient
6. ECLS for the cardiac patient
7. Bedside nursing care
8. ECMO specialist responsibilities
9. Preparing patient for transport

See Figures 1 and 2 below for the manikin setup.



Figure 1 – Manikin Setup



Figure 2 – Manikin Interaction

To assess the impact of simulation training on learning, the model for assessment and training developed and validated at WISER is utilized (DeVita et al, 2005). In this model, all learners have initial web-based didactic training, followed by live didactics. This includes video and live familiarization with the manikin. After didactics, the manikin training and assessment will be performed.

Subjects and Methodology

The model for assessment and training developed and validated at WISER will be utilized (DeVita et al, 2005). All learners will have initial web-based didactic training (within thirty days prior to live training), followed by summary live didactics on the day of training. This includes video and live familiarization with the manikin. Disease conditions and a set of 25 specific skills to be acquired and demonstrated on the manikin will be described during didactics, as well as portrayed through video demonstrations. These skills will be defined specifically as the curriculum is developed, but will include the following as an example: circulatory assessment, respiratory assessment, intubation, manual ventilatory assistance, chest compressions. These will be replicated in each of 5 different case-based scenarios (respiratory failure secondary to meconium aspiration, cardiorespiratory failure secondary to congenital heart defect (moderate and severe), congenital diaphragmatic hernia, and cardiorespiratory failure secondary to septic shock). Trainees will be randomized to receive 3 of the 5 scenarios, so there will be no repeats of scenarios for learners, and all will be distributed equally between first, second, and third episodes. After didactics, the initial assessment will be made on the manikin, and the number of skills performed correctly recorded, as well as whether the manikin survived. The second and third assessment will then follow, and the differences in outcomes between the three different episodes will be compared.

Subjects: All physicians, nurses, and perfusionists can participate in the curriculum. Clearance will be obtained from their institution/supervisors as needed so that there is no coercion to participate in the study. Hawaii, Pittsburgh, and San Antonio providers will be asked to participate.

Procedures: Once learners have enrolled in the course, they are given the URL for the Curriculum website and general instructions for registering. Once a participant has registered, they will be asked if they are participating in the evaluation and have not taken the pre-test. Once they give a “yes” response, they will be automatically directed to a pre-test to assess their knowledge prior to experiencing the modules. The test will be multiple-choice items covering information contained in the curriculum modules. Questions from each module’s post-test will be randomly selected for inclusion in the pre-test. Following completion of the pre-test, each learner will complete the modules.

Once a learner has reviewed the modules and feels comfortable with the information, he/she will be instructed to complete the two questionnaires associated with that module. A link will be provided on the contents page and on the conclusions page that will direct the learner to the questionnaires. The first is a “reaction” questionnaire to measure a learner’s level of satisfaction with the modules (See Sample Survey, Supplemental Documents). Following completion of the reaction questionnaire, each learner will answer multiple choice questions on the content of each module they just reviewed (See Sample Post-Test, Supplemental Documents). A score of 85% will be considered a sufficient passing score. It is estimated that it will require 1 hour to review each module and complete the associated questionnaires. This same process will be repeated with each module. The on-line modules consist of general cognitive knowledge, as well as the specific skills that will need to be acquired on the manikin, and provides pre-training for these specific skills.

On the day of training, summary didactics and manikin familiarity training will be provided. The manikin assessments will then be conducted as described above. The number of endpoints that are obtained in each assessment session will be recorded, in addition to survival of the manikin. The comparison of results between assessment episodes will be studied, to examine the effect of manikin training in acquiring skills and in preventing infant (manikin) mortality.

Twenty subjects are required for statistical significance, but up to 25 can complete both the on-line and/or manikin training. This permits some attrition in subjects between the web-based and manikin based curricula, should some subjects not complete the full program.

Online Web-based Didactic Training (Figure 3)

Website includes the following pages:

1. Start page – Register, CME Statement, IRB Informational Flyer
2. Pre-test
3. Modules with embedded test questions
4. Reaction survey

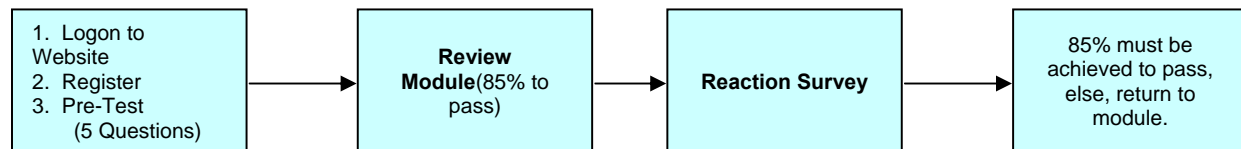


Figure 3 – Web-based Didactic Training

Manikin Training (Figure 4)

Website includes the following pages:

1. CME Statement, IRB Informational Flyer
2. Learner Satisfaction Survey
3. Curriculum Evaluation

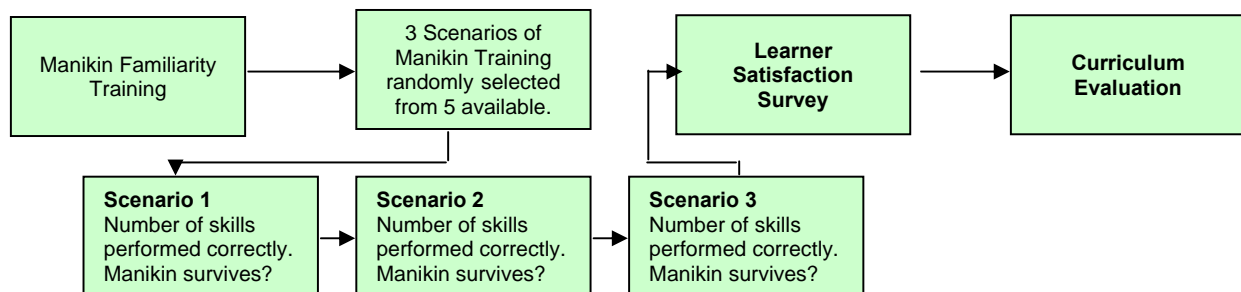


Figure 4 - Manikin Training

The manikin training is described in the *Facilitator Handbook*. Please have a look at Appendix A for details.

Measures

The data collected during the study allows answering the following research questions.

1. **Does task completion improve due to manikin training?** The design is a repeated

measures analysis of task completion (yes or no) between episode #1 and episode #2, with an effect size difference of 30% being investigated. This difference is based on WISER's previous research (DeVita et al, 2005), which demonstrated that task completion due to the effect of training was improved most between training sessions #1 and #2.

2. **Manikin Survival?** Does manikin survival improve due to manikin training?
3. **Learner Satisfaction?** Learner satisfaction surveys will be conducted post-training to determine learner satisfaction.
4. **Curriculum Evaluation.** A survey will also be completed for the combined educational curriculum as a whole.

Results

A total of 25 medical professionals have been recruited for the manikin study all of which have completed the online web-based didactic training session. 20 of which have completed the manikin portion of the study. Data from 2 participants have been excluded because of missing data points. The other 18 datasets have been analyzed in SPSS; the learner satisfaction survey and curriculum evaluation was completed by 17 participants. The results are listed below.

Research Question Q1)

A repeated measures analysis has been performed for scenarios 1-3. Please consider Table 1 for detail. With $p < .05$ we reject the Null Hypothesis. Results indicate that task completion has improved for repeated training sessions.

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Training	Sphericity Assumed	.230	2	.115	4.620	.017
	Greenhouse-Geisser	.230	1.654	.139	4.620	.024
	Huynh-Feldt	.230	1.809	.127	4.620	.020
	Lower-bound	.230	1.000	.230	4.620	.046
Error(Training)	Sphericity Assumed	.845	34	.025		
	Greenhouse-Geisser	.845	28.112	.030		
	Huynh-Feldt	.845	30.757	.027		
	Lower-bound	.845	17.000	.050		

Table 1 – Results Table for Manikin Training (Repeated Measure, Training)

Figure 5 shows the improvement in scores for task completion over scenarios 1-3. Note that 1.00 is the maximum score possible (100% correctness). On average, a passing grade of 80% was reached for scenarios 2 and 3.

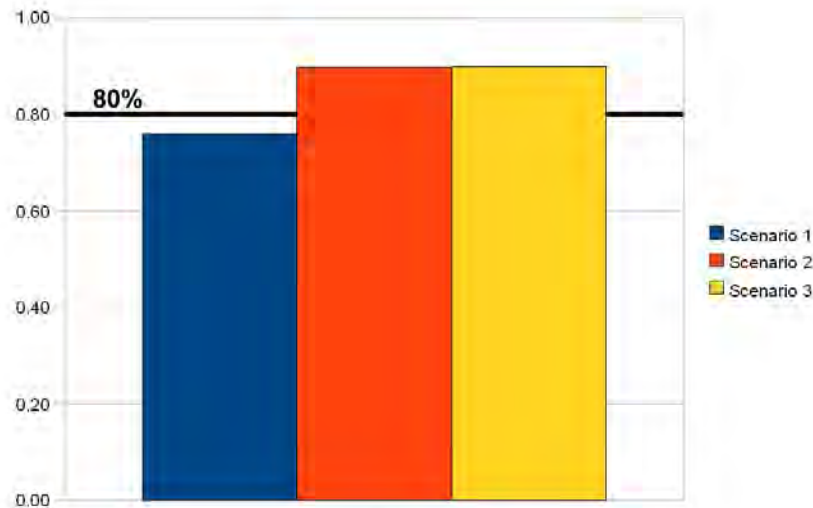


Figure 5 – Results Graph for Manikin Training (Scenarios 1 – 3)
n=18

Research Question Q2)

A passing score of 80% is used to determine the survival of a manikin. This permits the student to *pass* if no more than 1 critical event is missed, with 6 or 7 critical events identified per scenario. The student *fails* if the manikin does not survive by missing 2 or more critical events.

With $p < .05$ we reject the Null Hypothesis (see Table 2). Results indicate that manikin survival significantly improved for repeated training sessions.

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Training	Sphericity Assumed	1.037	2	.519	3.552	.040
	Greenhouse-Geisser	1.037	1.873	.554	3.552	.043
	Huynh-Feldt	1.037	2.000	.519	3.552	.040
	Lower-bound	1.037	1.000	1.037	3.552	.077
Error(Training)	Sphericity Assumed	4.963	34	.146		
	Greenhouse-Geisser	4.963	31.844	.156		
	Huynh-Feldt	4.963	34.000	.146		
	Lower-bound	4.963	17.000	.292		

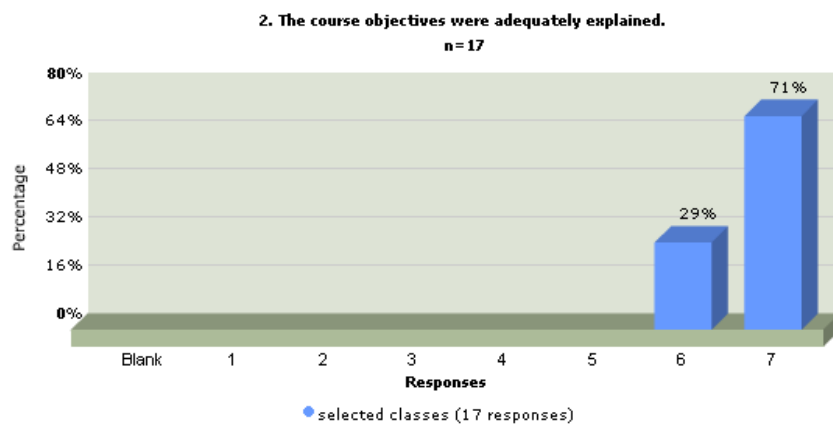
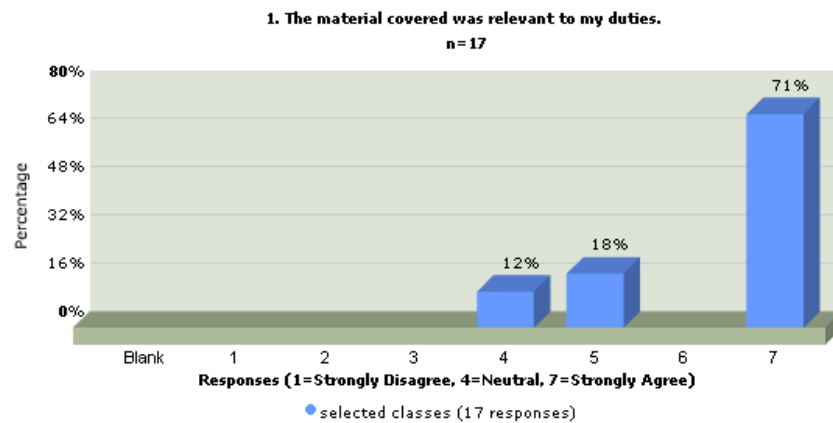
Table 2– Results Table for Manikin Training (Repeated Measure, Survival)

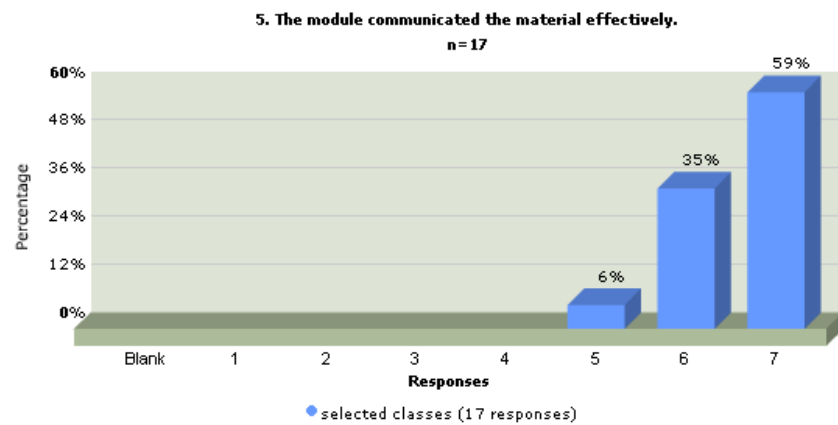
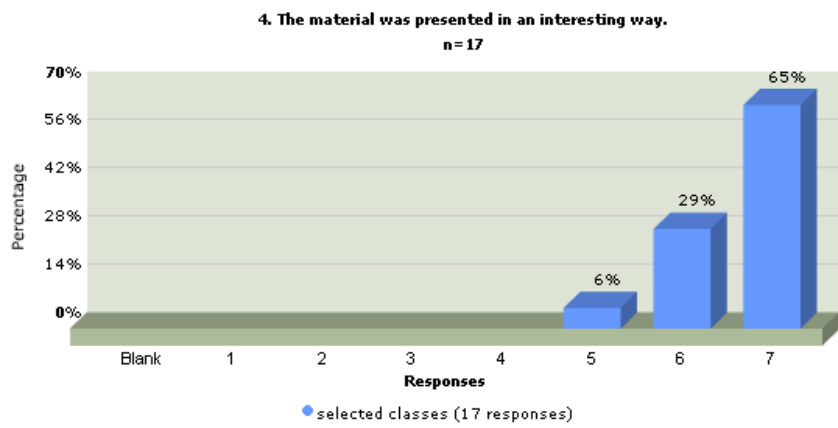
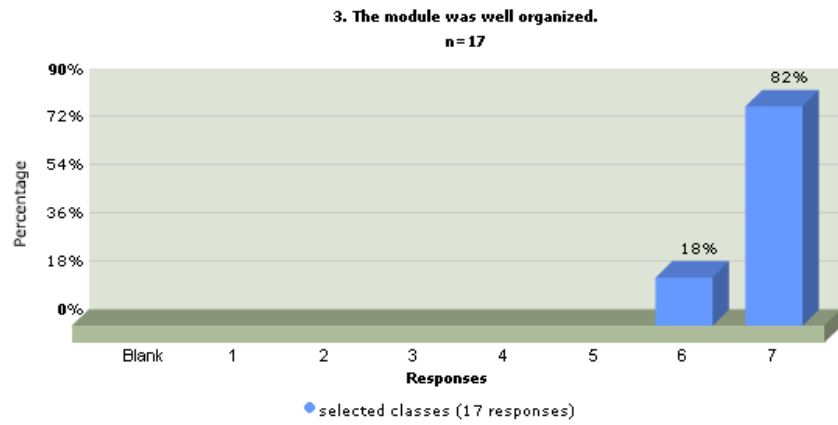
Figure 6 shows manikin survival over scenarios 1-3. On average, a passing grade of 80% was reached for scenario 3.

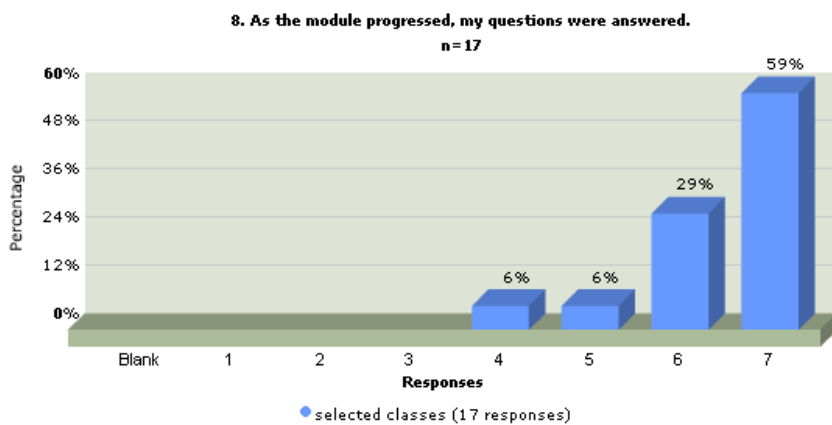
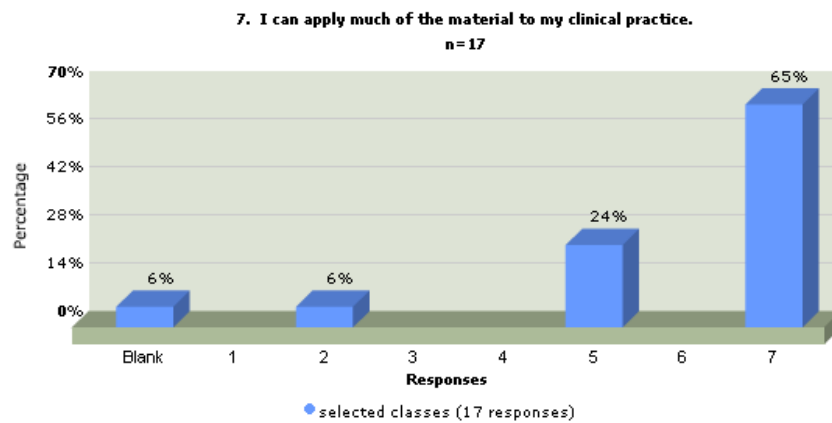
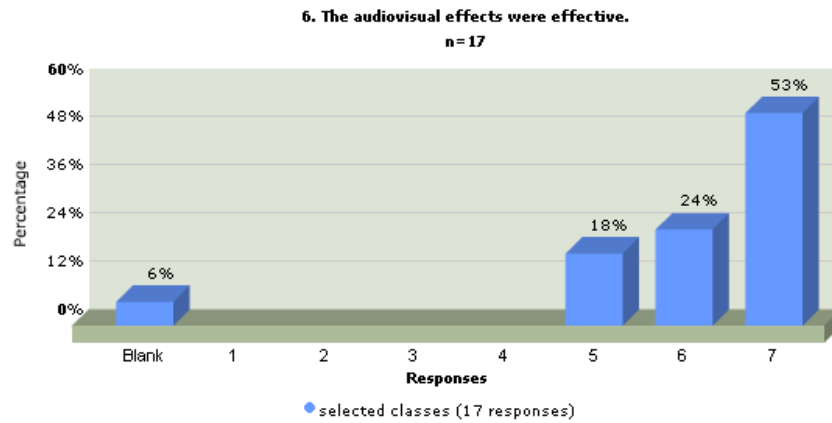
Figure 6– Results Graph for Manikin Survival (Scenarios 1 – 3)
n = 18

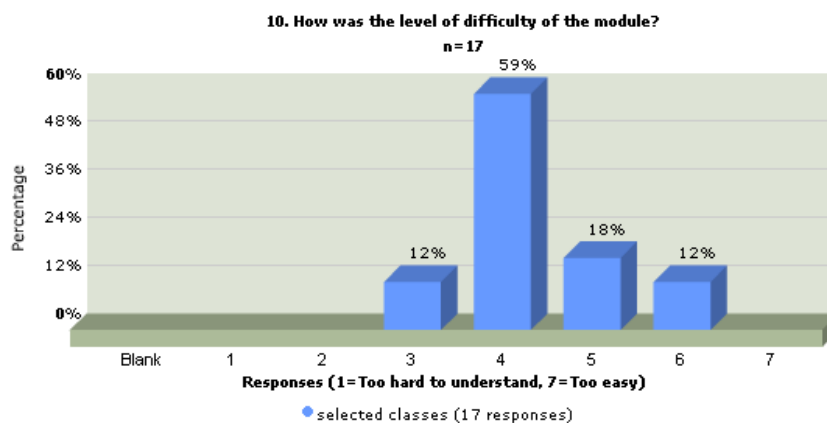
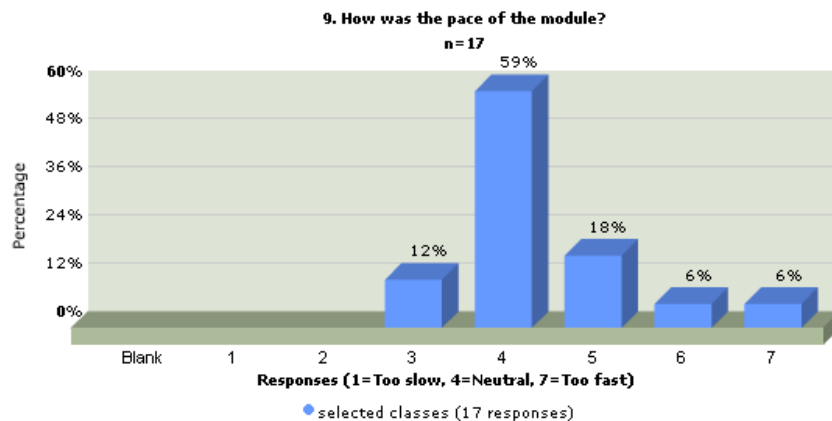
Research Question Q3)

The results of the Learner Survey are listed below. The survey has received favorable scores validating the relevance of the manikin training materials covered.





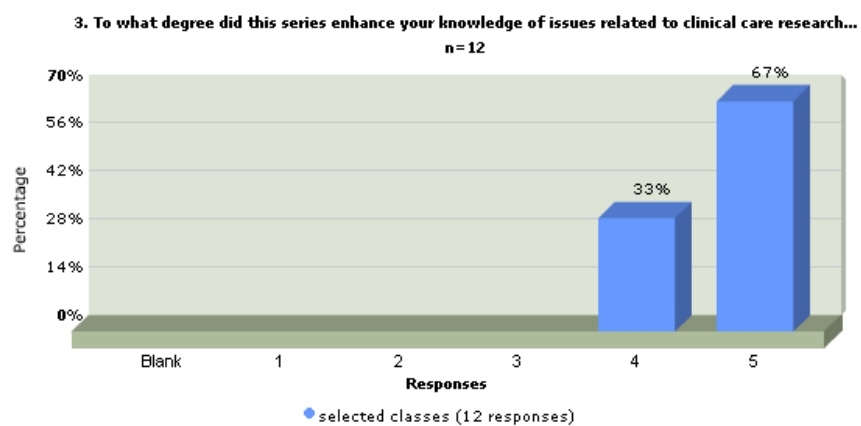
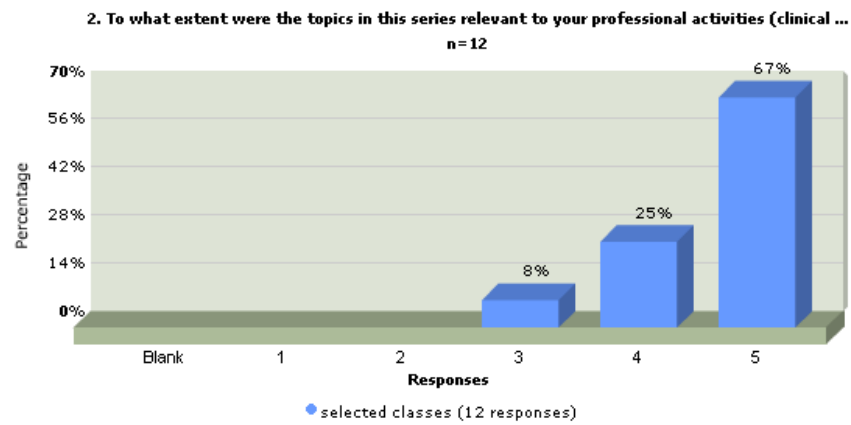
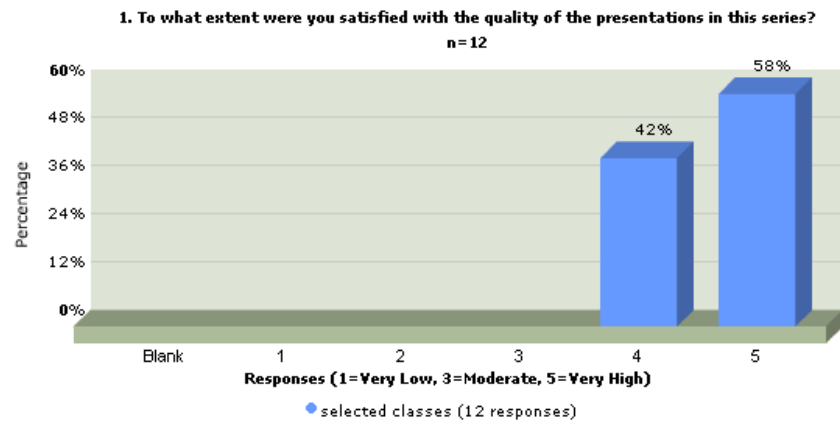




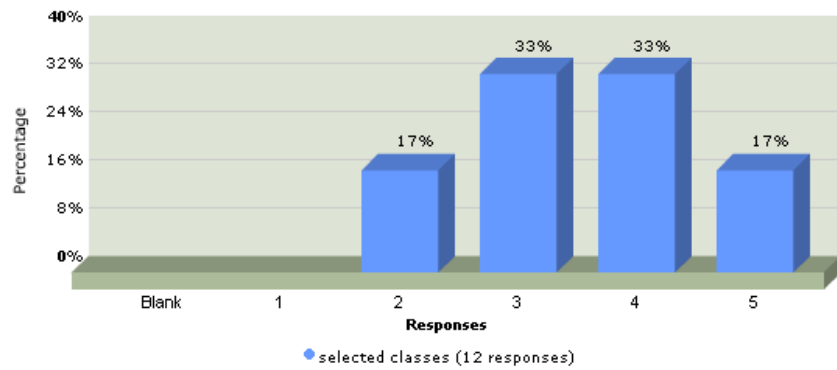
Research Question Q4)

The results for the curriculum evaluation are listed below. The curriculum evaluation questions were previously validated by 360 doctors for 17 CME presentations and have shown to be reliable with as few as 8 evaluations per CME course (Wood et al, 2005).

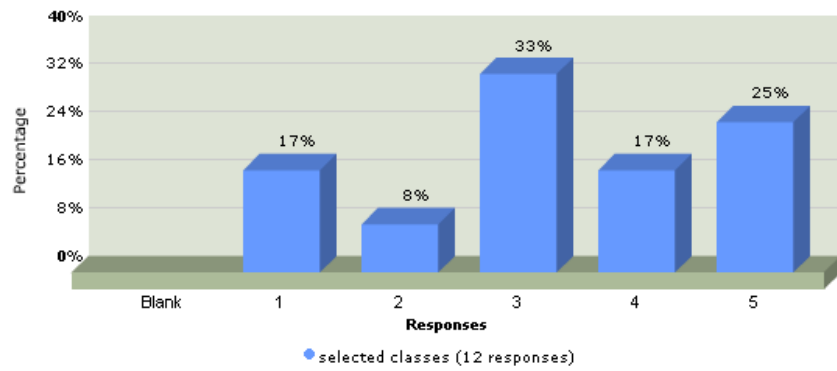
All questions except 4, 5, and 7 have an average score of 4.0 or higher on the 5-point Likert scale. The lower score for those three questions can be explained by the focus of the manikin study. The manikin training is geared towards practical application in a clinical environment rather than literature review, data analysis or ethics.



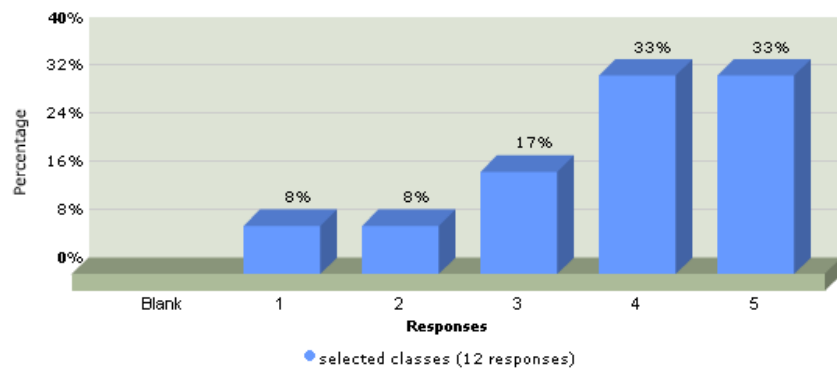
4. To what degree did this series enhance your ability to use the biomedical literature and best ava...
n=12



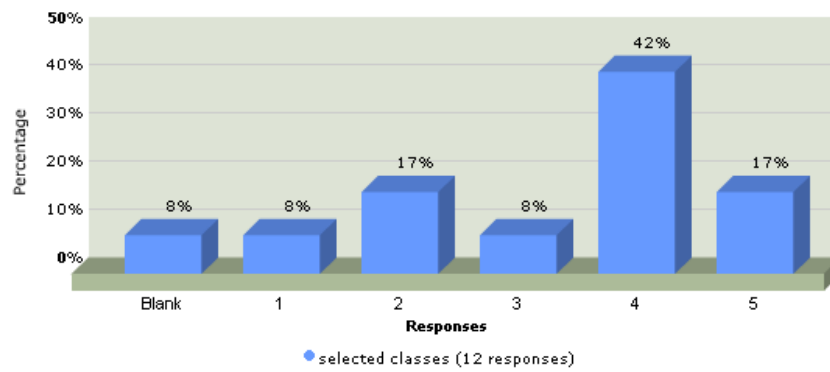
5. To what degree did this series enhance your ability to provide ethical and culturally sensitive c...
n=12



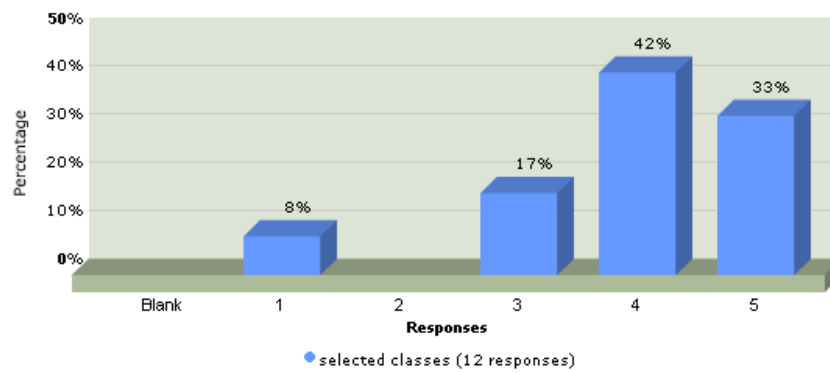
6. To what degree did this series enhance your ability to communicate with your patients and / or ot...
n=12



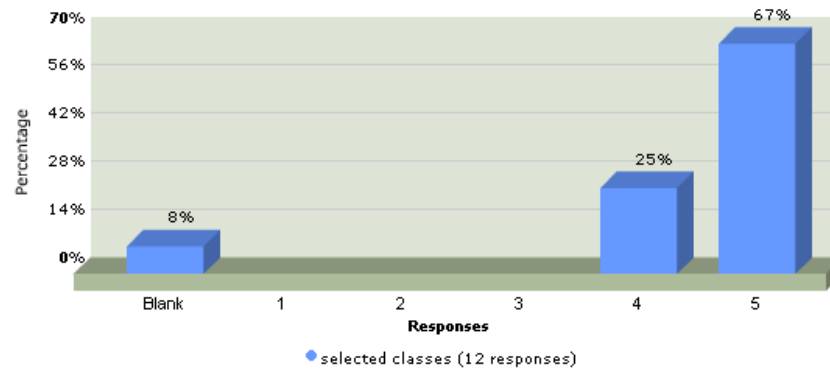
7. To what degree did this series enhance your ability to use health care data and other evidence to...
n=12

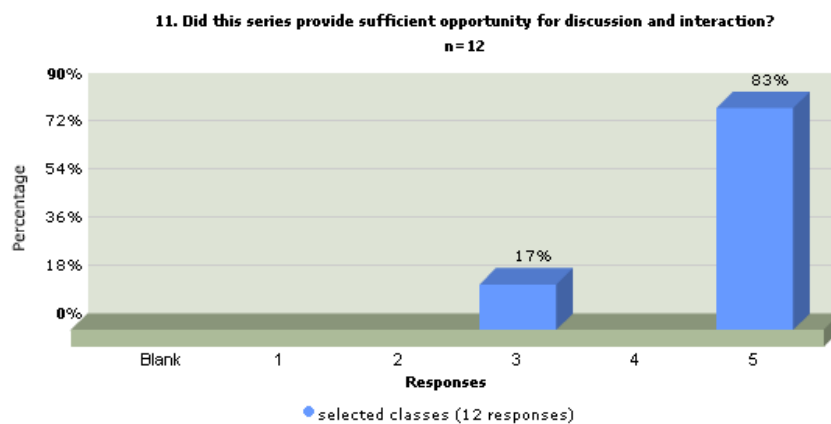
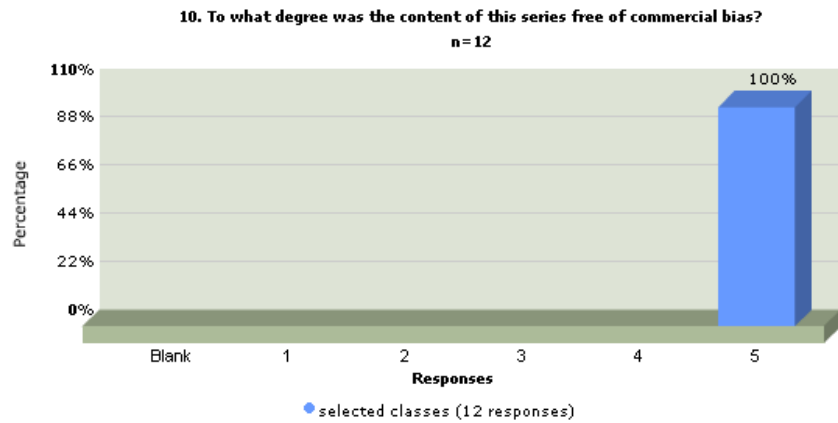


8. To what degree did this series improve your ability to work within the clinical or academic envir...
n=12



9. To what degree was this content of this series scientifically rigorous, unbiased and balanced?
n=12





Discussion

The manikin study demonstrated that Manikin-Based Simulation Training can be used effectively to improve advanced pediatric care skills acquisition, with statistical improvement between sessions ($p < .05$). There was no discernible improvement between Session 2 and Session 3 (Figure 5). This is similar to the results reported by DeVita et al., with the greatest improvements between the first and second training session. This implies that only two training sessions may be necessary. However, with respect to manikin survival, Session 3 (89% with passing score) was necessary for the group to have an overall passing score $\geq 80\%$ (Figure 6), as compared to lower passing rates in Session 1 (56%) and Session 2 (78%).

The number of repetitive training scenarios per a single training session is an important issue. Training time is limited by both competing curricula and regulations for student training time (e.g., 80 hour work week for resident physicians). This limits the amount of time for any type of training. If only one or two practice sessions are necessary, eliminating a third or fourth session will save time for trainees and be more cost effective for the institution. However, it is unknown how many sessions should be accomplished once a plateau in training outcomes is reached for a given training session. How repetition impacts skills retention over short and long-term time

periods and satisfaction of the learners are important issues that remain largely unanswered. This could be area to evaluate with future research.

Manikin simulation has several advantages compared to standard didactic learning. Current simulation technology allows for the simultaneous integration of cognitive and procedural skills. Full scale human simulators have realistic functions such as breathing, heart and lung sounds, and palpable pulses. Procedures can be performed on these manikins, such as intubation, chest tube placement, and intravenous or central catheter placements. They have realistic physiologic monitoring parameters including heart rate, respiratory rate, blood pressure, temperature, and pulse oximetry that are displayed on a monitor as they would for a similarly monitored patient. Pharmacologic interventions are also accomplished, with exact doses and the related physiologic reactions experienced by the manikin and viewed on the monitor.

These advanced functions allow manikins to be programmed to simulate multiple clinical scenarios and respond to therapeutic interventions. For example, the infant simulator can be programmed to represent a neonate with severe shock, including decreased pulses, high heart rate, and low blood pressure. The trainee will be able to assimilate their physical exam findings with vital signs and recognize a neonate in severe shock. The trainee can then make a therapeutic decision and execute treatment on the manikin. The ability of trainees to recognize, evaluate, and execute treatment with simulation makes this educational tool particularly suited for ECLS education, both in the pre-ECLS and post-ECLS arena.

In pre-ECLS situations, the key is recognition of the critically ill patient with shock and/or sepsis who requires ECLS as well as optimizing the clinical status of this patient. Early recognition and treatment of the critically ill neonate is vital to survival. Han et al looked at mortality of pediatric/neonatal patients in shock being treated by community physicians. The study demonstrated that if shock was reversed, patients had a 96% survival rate; but for each hour of persistent shock, there was a > 2-fold increase in mortality. For Hawaii and Pacific Rim physicians, simulation will give them the opportunity to recognize that the patient is in shock, and then provide the tool to train on management techniques to stabilize the patient towards recovery, or to be prepared for ECLS referral if the patient's condition does not improve. Pre-ECLS patient scenarios can be practiced multiple times in a simulated environment, where trainees can learn and errors do not cause patient morbidity or mortality.

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Appendix A – Facilitator Handbook

Facilitator Handbook

Please do not remove

ASSESSMENT AND INTERVENTION FOR PEDIATRIC PATIENTS IN EMERGENCY SITUATIONS (AI PED EM)



By clicking this hyperlink, you will be re-directed to the Hanuola ECMO Program of Hawaii website.

1. Please click **Register** if you are first time user to the Hanuola website.
2. If you have already created an account in the Hanuola website, please enter the username and password.
3. If you have any questions, please email help@simtiki.org or call administrator Cami Mikami @ 808-692-1085, or Simulation Specialist, Kris Hara @ 692-1096.

<http://www.tri.jabsom.hawaii.edu/manikinstudy/>

1. complete Hanuola website
2. manikin scenarios
3. simtiki survey/evals

SURVEYS/EVALUATIONS	
VIEW SURVEY/EVALUATION	
Post-class Survey: Learner Survey	
Post-class CME Evaluation	
Post-class Nursing CEU	

Pre-instructions from Facilitator to Student

Assessment and Interventions for the Critically Ill Patient Evaluation

Manikin Introduction

Manikin Introduction (sim specialist will assist)

Manikin sounds

breath & heart tones

pulses

airway – don't sweep the tongue

pupils

B/P cuff, oximeter, electrodes attached. Cycle B/P by request

Equipment available

Facilitator Script

1. Welcome to the Assessment and Interventions for the Critically Ill Pediatric Patient Evaluation study. Thank you for helping us evaluate the educational effectiveness of the modules and the simulation experience. This is NOT an evaluation of your abilities. Your performance is confidential and will not be shared.
2. You will be acting in the role of a responder in a triage treatment area. Someone has just placed cardio-respiratory monitors on the patient.
3. Each scenario is 6 minutes.
4. I will be your assistant. There are some tasks that you'll initiate (like bagging the patient) then I will take over. If there are tasks you feel need to be done, but are not familiar with (for example intubation), ask for help, but I may ask you to choose the equipment and put it at the bedside for me.
5. You can ask me questions at anytime. I may or may not have the answers. I might ask you a question to clarify your thought process.
6. Ask me if you need an updated blood pressure reading. The blood pressure will not automatically cycle.
7. Please "think out loud" during the simulation session. Verbalize what you're doing, the physical findings you are seeing. Say what you think is going on with the patient.
8. Once the scenario is completed, I will debrief you and we'll learn together. Please do not discuss the specifics of the scenarios outside of this room. This will keep the experience fresh for other participants.
9. Remember, you are not in the hospital. You are one of the first responders to the scene or triage tent. There is no lab available. The equipment you see is all we have.
10. RELAX! This is a learning experience for all of us and we want you to have FUN with the challenge!

Notes:

1. If there are additional checklist items to be done, the sim specialist will continue the scenario to the 6-minute time limit.
2. Allow the participant to begin BVM so the manikin can capture the rate. The sim specialist will let you know when to take over BVM.
3. Allow the participant to choose the intubation supplies : ETT, stylet, blade.
4. If you are utilizing a walkie-talkie to communicate with the sim specialist, please

remember to press the button on your headset a second before you speak.

AI PED ER Participant Random Generator 1						
	Name	Pre course material	POST course material	A	B	C
1				4	2	3
2				4	3	2
3				4	3	1
4				3	5	2
5				3	2	5
6				5	1	4
7				3	4	5
8				5	2	1
9				2	5	4
10				3	1	4
11				2	4	3
12				2	1	4
13				3	5	1
14				1	2	5
15				4	1	3
16				2	3	5
17				2	5	1
18				2	4	3
19				5	4	3
20				4	1	5
21				1	4	5
22				3	1	2
23				2	1	3
24				5	2	1
25				1	5	4

1 –Brain Injury SimTiki.scb

Witnessed accidentally dropped by mother down a flight of stairs. The patient has been put on a cardiorespiratory monitor and pulse oximetry.

1 Brain Injury SimTiki

ABC

- Critical Events
 - BVM at 20-35 BPM
 - Place IO
 - Administer 100cc res. fluid push
 - Intubate airway
 - Identify spinal cord shock
 - Continued fluid res. and pressors
- Airway and Breathing
 - Apply C-Spine stabilization
 - Chin lift/jaw thrust
 - Apply hi-flow oxygen
 - Reassess airway
- Circulation
 - Assess femoral or brachial pulse
 - Ask for blood pressure
 - Reassess circulation
- Intubation
 - Choose 3.5 cuffed or uncuffed ETT
 - Choose Miller 1 or 2 blade
 - Choose appropriate stylet
 - Use C-Spine precautions during intubation
 - Verbalize need for RSI with tight-head precautions
- Disability and Exposure
 - Roll patient with C-Spine precautions
 - Assess temperature
- Repeated Events
 - BVM
 - Place IO
 - Fluid push
 - Intubate
 - Continued fluid and pressors

Verbal information given to trainee if asked:

Infant weight is 5 kg
No significant past medical history
Infant is flaccid
Infant is unresponsive to deep pain
Infant is non-verbal
Infant pupils are non reactive
Infant capillary refill is 5 seconds
Infant is cool with mottled extremities
Infant hematocrit is 18
Infant CBG give you pH of 7.10 and base deficit of -12

Facilitator information to give to trainee:

When asked, infant has hematoma, abrasions to right posterior occiput

2 – Blast IED Injury.sce

Amputated limb w/ bloody towel under limb, blood splattered cloths.
15 y/o brought into triage after being found in the debris after a bombing. He was thrown approximately 20 feet and is unresponsive. He has obvious blast injuries with loss of left limb below the knee. The patient has been put on a cardiorespiratory monitor and pulse oximetry.

2 Blast IED Injury.sce

ABC

- [-] Critical Events
 - BVM at 10 - 15 BVM
 - Place IO/IV
 - Administer 1 Lt. resuc. fluid
 - Intubate airway
 - Identify blood loss as L lower limb amputation
 - Tourniquet and continued fluid resusc./surgery
- [-] AIRWAY AND BREATHING
 - 1. Apply C-spine stabilization
 - 2. Chin lift/jaw thrust
 - 3. Apply hi-flow oxygen
 - 4. BVM at 10 - 15 breaths per minute
 - 5. Reassess airway
- [-] CIRCULATION
 - 1. Assess central pulse
 - 2. Ask for blood pressure
 - 3. IV/IO placed
 - 4. Administer 1 Lt. resuc fluid push
 - 5. Reassess circulation
- [-] INTUBATION
 - 1. Choose 7 ETT
 - 2. Choose Miller 2 or Mac 3-4
 - 3. Choose appropriate stylet
 - 4. Intubate airway
 - 5. Use C-spine precautions during intubation
 - 6. Verbalize need for RSI with tight-head precautions
- [-] DIABILITY AND EXPOSURE
 - 1. Roll patient with C-spine precautions
 - 2. Assess temperature
 - 3. Identify source of ongoing blood loss
 - 4. Identify correct treatment of ongoing blood loss
 - 5. Reassess diability and/or exposure
- [-] Repeat Events
 - BVM
 - IO/IV
 - Admin. fluid
 - Intubate
 - Identify L lower limb amputation
 - Tourniquet/Fluid/Surgery

Verbal information given to trainee if asked:

Teen weight is 50 kg

No significant past medical history

Teen is unresponsive to deep pain

Teen is non-verbal

Teen has responsive pupils

Teen capillary refill is 4 seconds

Teen is cool with mottled extremities

Teen hematocrit is 16

Infant ABG give you pH of 7.12 and base deficit of -10

Facilitator information to give to trainee:

When asked there is profuse blood loss from amputated left lower limb

3 – Abdominal Trauma SimTiki

seat belt bruise
Rear seat passenger in MVC
restrained by lap belt and not in car
safety seat. The patient has been
put on a cardiorespiratory monitor
and pulse oximetry.

Verbal information given to trainee if asked:

Child weight is 10 kg
No significant past medical history
Child is unresponsive to deep pain
Child is non-verbal
Child left pupil is non reactive
Child capillary refill is 4 seconds
Child is cool with mottled extremities
Child hematocrit is 26
Child CBG reads a pH of 7.12 and base deficit of -10 and all else is unreadable

Facilitator information to give to trainee:

Trainee should choose a 4.0 or 4.5 ETT but must use a 3.5 ETT to intubate
manikin because of manikin airway size
When asked the abdomen is getting more tense and there is discoloration over
the left lower flank

3 - Abdominal Trauma SimTiki

ABC

- Critical Events
 - BVM at 20-35 BPM
 - Place IO
 - Administer 100cc res. fluid push
 - Intubate airway
 - Identify abdominal trauma
 - Suggest surgical intervention/ongoing resuscitation
- Airway and Breathing
 - Apply C-Spine stabilization
 - Chin lift/jaw thrust
 - Apply hi-flow oxygen
 - Reassess airway
- Circulation
 - Assess femoral or brachial pulse
 - Ask for blood pressure
 - Reassess circulation
- Intubation
 - Choose 3.5 cuffed or uncuffed ETT
 - Choose Miller 1 or 2 blade
 - Choose appropriate stylet
 - Use C-Spine precautions during intubation
 - Verbalize need for RSI with tight-head precautions
- Disability and Exposure
 - Roll patient with C-Spine precautions
 - Assess temperature
- Repeated Events
 - BVM
 - Place IO
 - Fluid push
 - Intubate
 - Continued fluid and pressors

4 – Motor Vehicle SimTiki.scb

Comment:

Blood Right Ear, Left femur deformity
15 month old infant restrained passenger in a high-speed
T-bone MVC. Found unresponsive with blood from right ear.

4 - MVA Sim Tiki

ASL

- [-] Critical Events
 - BVM at 20-35 BPM
 - Place IO
 - Administer 100cc res. fluid push
 - Intubate airway
 - Identify spinal cord shock
 - Continued fluid res. and pressors
 - Identify L lower limb deformity
- [-] Airway and Breathing
 - Apply C-Spine stabilization
 - Chin lift/jaw thrust
 - Apply hi-flow oxygen
 - Reassess airway
- [-] Circulation
 - Assess femoral or brachial pulse
 - Ask for blood pressure
 - Reassess circulation
- [-] Intubation
 - Choose 3.5 cuffed or uncuffed ETT
 - Choose Miller 1 or 2 blade
 - Choose appropriate stylet
 - Use C-Spine precautions during intubation
 - Verbalize need for RSI with tight-head precautions
- [-] Disability and Exposure
 - Roll patient with C-Spine precautions
 - Assess temperature
- [-] Repeated Events
 - BVM
 - Place IO
 - Fluid push
 - Intubate
 - Continued fluid and pressors

Verbal information given to trainee if asked:

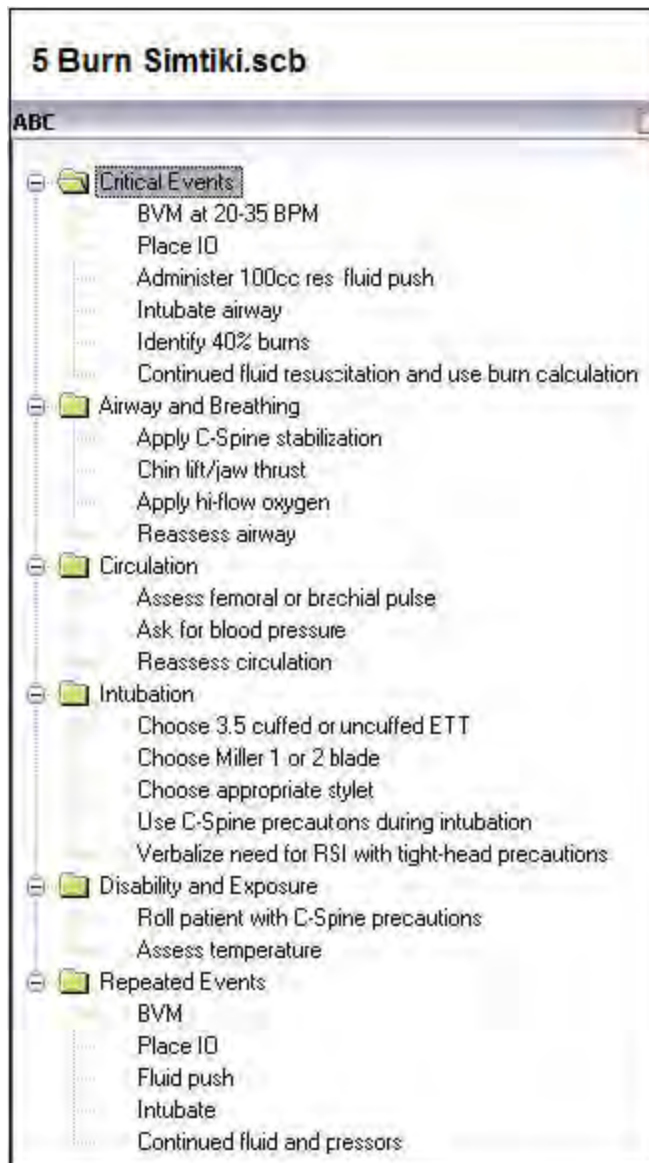
Child weight is 12 kg
No significant past medical history
Child is unresponsive to deep pain
Child is non-verbal
Child left pupil is non reactive
Child capillary refill is 4 seconds
Child is cool with mottled extremities
Child hematocrit is 26
Child CBG reads a pH of 7.12 and base deficit of -10 and all else is unreadable

Facilitator information to give to trainee:

Trainee should choose a 4.0 or 4.5 ETT but must use a 3.5 ETT to intubate manikin because of manikin airway size
When asked the left femur deformity is getting larger and more tense

5 – Burn Simtiki.scb

torso burns, soot on face
 Pulled from a burning building. The infant has weak hoarse cry, soot on face and singed eyelashes. The infant is tachypneic. The patient has calculated 40% BSA of second and third degree burns. The patient has been put on a cardiorespiratory monitor and pulse oximetry.



Verbal information given to trainee if asked:

Child weight is 8 kg
 No significant past medical history
 Child is unresponsive to deep pain
 Child is crying hoarsely
 Child pupils are reactive
 Child capillary refill is 4 seconds
 Child is cool with mottled extremities

Facilitator information to give to trainee:

Trainee should choose a 4.0 or 4.5 ETT but must use a 3.5 ETT to intubate manikin because of manikin airway size

Clothing

Camo uniform fabric under manikins to help our clinicians disengage from hospital based mentality.

Street clothes

- 1 – Brain Injury SimTiki w/ abrasion to right posterior occiput
- 2 – Blast IED Injury w/ amputated leg and ‘bloody’ pants, towel under leg.
- 3 – Abdominal Trauma SimTiki w/ seatbelt sign – either makeup or red cello
- 4 – Motor Vehicle Simtiki – red blood (red ace bandage piece) Right ear, Left leg twisted
- 5 – Burn Simtiki – red cello on back, black smudge around nasal, oral area

SimBaby Equipment List:

BVM (self inflating)

CO2 detector

Laryngoscope handle

Blades: Miller 0,1, 2 , Mac 3,4

ETT: 3, 3.5, 4, 4.5, 5

Baby & adult stylet

Non-rebreather mask, cannula

500ml NaCl IV bag

1 liter NaCl IV bag

IO

IV tubing

IV insertion kit

Cervical collar or similar

blanket

SimMan Equipment List:

BVM appropriate for manikin size

CO2 detector

Laryngoscope handle

Blades: Miller 0,1, 2 , Mac 3,4

ETT: 5, 6, 7

Baby & adult stylet

OPA

NPA

Non-rebreather mask, cannula

500ml NaCl IV bag

1 liter NaCl IV bag

IO

IV tubing

IV insertion kit

Cervical collar

Tourniquet (either military or bandage)

Appendix C.1

Validation of ECMOjo, a Computer Simulator for Extracorporeal Membrane Oxygenation (ECMO)

Christoph Aschwanden, PhD

Mark Ogino, MD

Lawrence Burgess, MD

Abstract

Objective: Validation of ECMOjo, a computer simulator and trainer for extracorporeal membrane oxygenation (ECMO). Execute a study to compare ECMOjo training with conventional didactic classroom training.

Summary Background Data: The ECMOjo computer simulator has been built by a development team of ECMO experts, medical practitioners and software engineers. No previous research data is available as to ECMOjo's suitability for simulation and training. ECMO practitioners currently undergo standard didactic training coupled with laboratory training to learn the mechanics of ECMO.

Methods: A total of 51 medical professionals were enrolled to participate in an ECMO skills acquisition study. Subjects were randomized into two groups. One group doing conventional classroom learning and the other training on ECMOjo over the same period. Both groups were assessed using three wet-lab scenarios after their training, with wet-lab results compared between groups.

Results: No significant difference has been observed between training on ECMOjo and a conventional classroom session. Results indicate ECMOjo and classroom learning are both equivalent for training of ECMO.

Materials

ECMOjo is a computer simulator that visualizes ECMO circuit components including associated medical variables, and allows manipulation of the circuit. The advantages of the virtual ECMO circuit over high fidelity simulators include: availability of real-time circuit data (e.g. flows, SvO₂, Pre- and Post-membrane gas) and laboratory data, the ability to manipulate circuit components in reaction to clinical circumstances, the integration of ECMO circuit and patient variables, and the potential for wide-spread availability as a computer-based educational tool.

The test model has been built by a development team from the Telehealth Research Institute (TRI), part of the John A. Burns School of Medicine (JABSOM) in collaboration with medical practitioners and ECMO experts from Kapi'olani Medical Center's Hanuola ECMO Center in Hawaii. The source and build files are open-source and available via SourceForge.net under the project "ECMOjo".

Figures 1 and 2 show screenshots of the current version of ECMOjo.

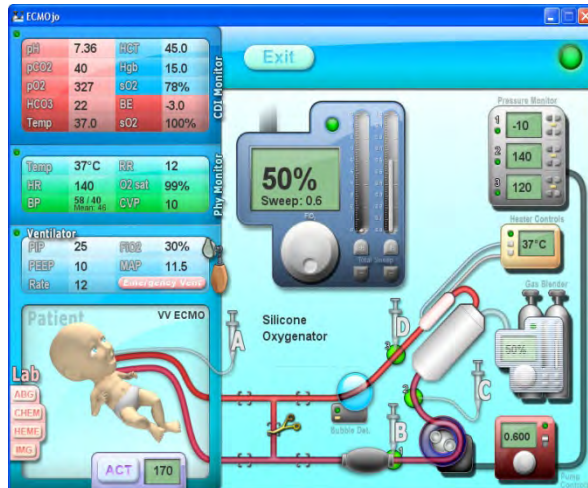


Figure 1 - Interactive GUI screen



Figure 2 – Scenario Selection Screen

Subjects and Methodology

Figure 3 summarizes the study's research design and methods. ECMOjo study participants initially fill out a demographic survey and go through the pre-assessment and conduct a circuit check in the wet lab. Following the pre-assessment, subjects are randomized into one of two groups. One group (comparison) continuing with conventional classroom learning, and the other (experimental) training on ECMOjo over the same time period. The training scenarios used in ECMOjo are also used for the classroom learning of the comparison group, and contain the skills that are assessed during the wet lab. By keeping the content the same, ECMOjo could be isolated as the learning variable. Please have a look at **Appendix A** for ECMOjo scenarios utilized during the study.

Following these interventions, skills are assessed in the wet-lab. The wet lab consisted of 3 scenarios, with 10 skills (appropriate interventions) evaluated in each scenario. Additionally, both groups complete a reaction questionnaire and learning environment questionnaire that includes self-efficacy, before and after the wet-lab assessment.

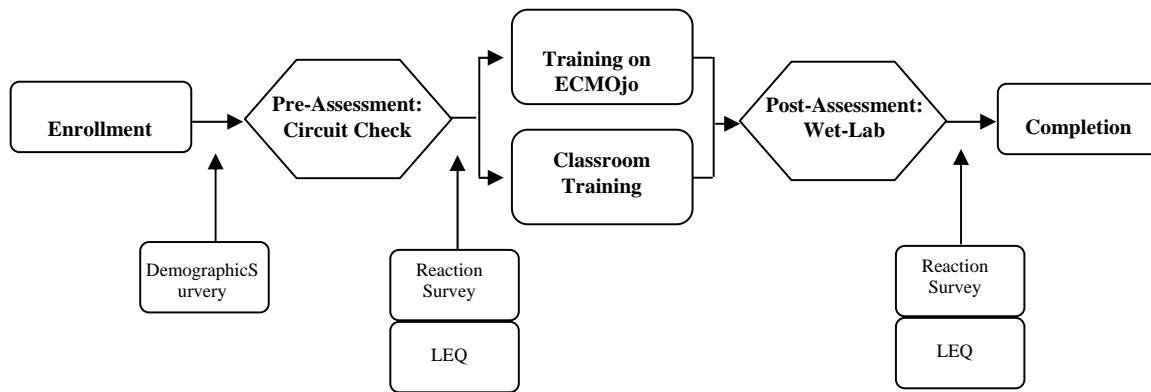


Figure 3 - Study Design

Please have a look at **Appendix B** for the Pre-Assessment Circuit Check as well as the Post-Assessment Wet-Lab scenarios.

Measures

The data collected during the study allows evaluation of the following research questions.

5. The most significant research question being investigated in this study is whether ECMOjo training improves the acquisition of ECMO skills over conventional classroom learning, as assessed in performance during wet-lab training. In the comparison between the ECMOjo group and didactic training group, a nonparametric test for correlation on paired data, Pearson's Chi-square analysis, will be used. A chi-square probability of .05 or less is will be justification for rejecting the null hypothesis that there is no difference between the two groups as assessed in the wet-lab evaluation.
6. To analyze whether iterative training exposures will result in a measurable change in self-efficacy, as compared between the ECMOjo group and classroom learning group, the overall score for each LEQ scale will be presented as the total score of the items in the scale. Higher scores will indicate more positive answers.
7. To analyze whether experts will perform better than novices on ECMOjo, Pearson's Chi-square analysis, will be used. A chi-square probability of .05 or less is will be justification for rejecting the null hypothesis that there is no difference between the novices and experts as assessed in the number of correct skill completed in the ECMOjo scenarios.
8. To analyze whether ECMOjo performance will correlate with wet-lab performance, Pearson's r will be used. This statistic will measure the linear relationship between ECMOjo performance and wet-lab performance (i.e. does performance on ECMOjo predict performance in the wet-lab). The statistical significance of r , a p-value of less than .05, will be used to determine if there is a statistically significant relationship between ECMOjo and wet-lab performances.

Results

A total of 51 medical professionals have been recruited for the ECMOjo skills acquisition study from hospitals that host ECMO centers. From the 51 datasets collected, 7 have been excluded because of (a) non-medical personnel, (b) missing data, and (c) problems during data recording such as interruption (e.g., beeper) or lack of attention. The following were excluded: 5 non-specialists in the ECMOjo group and 2 non-specialists in the lecture group. Forty-four datasets

have been analyzed in SPSS. The results are listed below. Twenty-four out of the 44 participants were ECMO specialists. The participants were randomly assigned to either the ECMOjo or lecture group, with an equal number of experts and novices assigned per group. For the 44 analyzed datasets, there were 13 ECMO specialists and 7 non-specialists that underwent ECMOjo training, and 12 ECMO specialists and 12 non-specialists that were assigned to the lecture group.

Table 1 displays the overall demographic of the people that enrolled in the research study.

Nurses	15
Respiratory Therapists	7
Perfusionists	5
Physicians	10 (Fellows: 6, Faculty: 4)
<i>Other</i>	7

Table 1 – Demographics

Research Question Q1)

The analysis of the wet-lab post-assessment between the two training modalities shows a chi-square probability higher than .05. We therefore accept the null hypothesis: there is no difference in training between ECMOjo and didactic classroom training (Figure 4).

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	24.169 ^a	22	.338
Likelihood Ratio	32.907	22	.063
Linear-by-Linear Association	.029	1	.864
N of Valid Cases	44		

Figure 4 – Chi-square (Training)

Figure 5 depicts the average scores for the final wet-lab assessment after training with either didactic lecture (blue) or ECMOjo (orange). The maximum possible score per scenario is 1.0 (=100%). Each participant went through three scenarios, so the maximum possible **Total** score is 3.0. **Error** represents the error score/discouraged intervention per scenario (0 = no error, 1 = one or more critical errors).

Please note, although the ECMOjo group made less errors in the wet-lab assessment, the error rate was not found to be statistically significant.

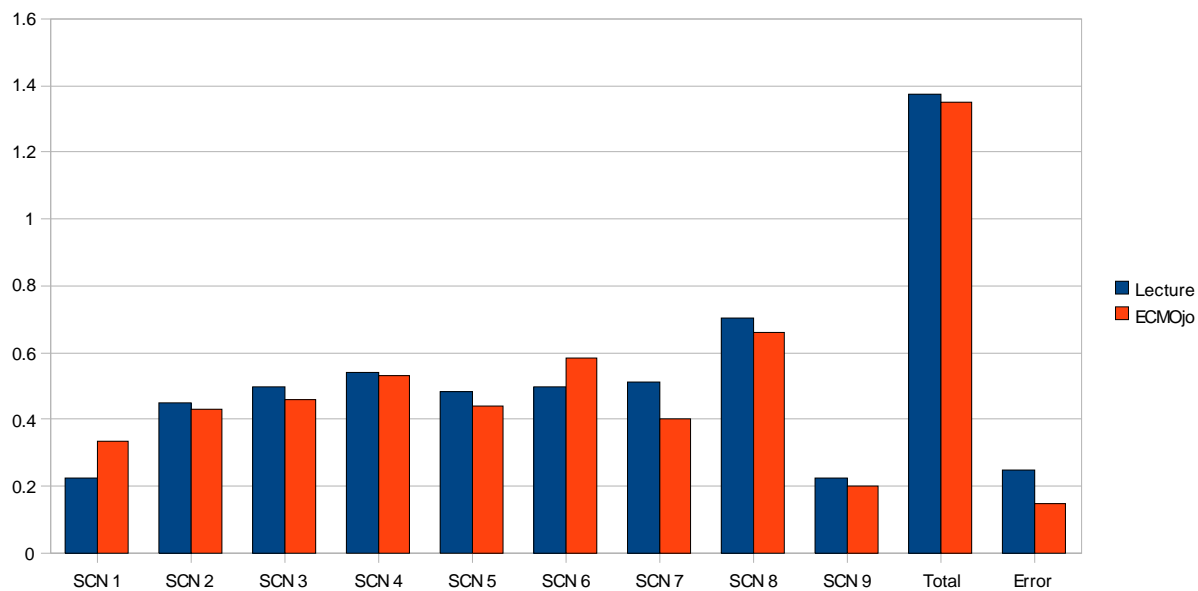


Figure 5 – Wet-Lab Assessment Scores (Lecture vs. ECMOjo)

Research Question Q2)

A repeated measures analysis of Learning Environment Questionnaire (LEQ) scores yields differences $p < .05$ for all LEQ questions except question 1 and 8. Scores have been recorded as equal or higher in all cases. Please consider Figure 6 for details.

Source	Measure	Training	Type III Sum of Squares	df	Mean Square	F	Sig.
Trained	Q1	Linear	.570	1	.570	3.018	.090
	Q2	Linear	.744	1	.744	7.344	.010
	Q3	Linear	2.616	1	2.616	5.262	.027
	Q4	Linear	5.628	1	5.628	20.785	.000
	Q5	Linear	4.651	1	4.651	26.582	.000
	Q6	Linear	2.279	1	2.279	12.398	.001
	Q7	Linear	.744	1	.744	5.947	.019
	Q8	Linear	.105	1	.105	1.835	.183
Error(Trained)	Q1	Linear	7.930	42	.189		
	Q2	Linear	4.256	42	.101		
	Q3	Linear	20.884	42	.497		
	Q4	Linear	11.372	42	.271		
	Q5	Linear	7.349	42	.175		
	Q6	Linear	7.721	42	.184		
	Q7	Linear	5.256	42	.125		
	Q8	Linear	2.395	42	.057		

Figure 6 – Repeated Measure LEQ (Training)

Figures 7 and 8 depict the pre-and post training LEQ scores for classroom training and training on ECMOjo.

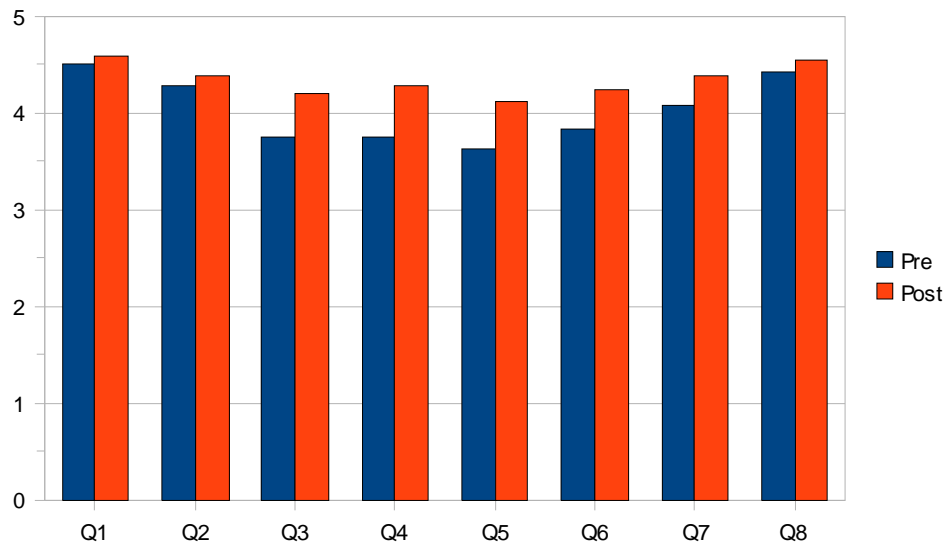


Figure 7– LEQ Scores for Classroom Training (Pre & Post)

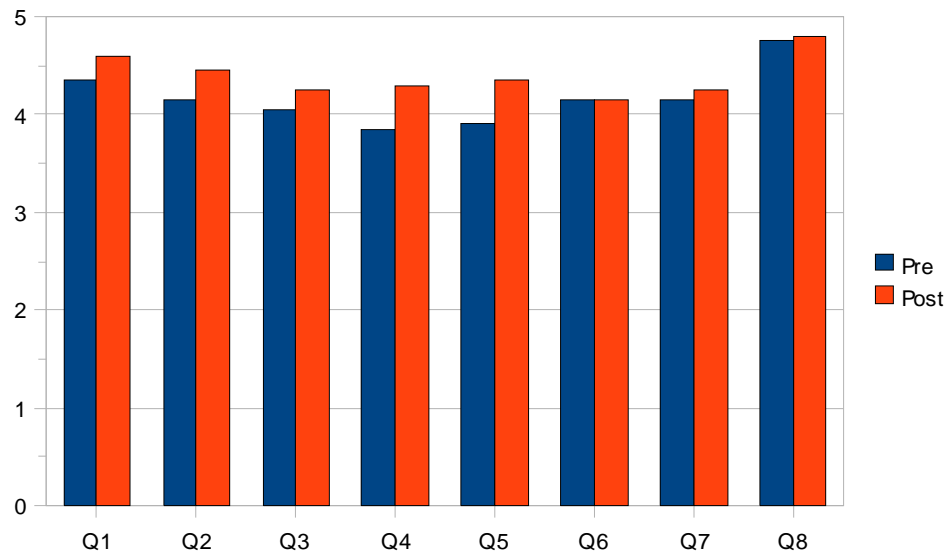


Figure 8– LEQ Scores for ECMOjo Training (Pre & Post)

Research Question Q3)

No difference in performance between novices and experts has been observed for training on ECMOjo. A participant has been determined an expert based on (i) primary specialty and/or (ii) years being an ECMO practitioner.

For the 44 analyzed datasets, there were 13 ECMO specialists, and 7 non-specialists that underwent ECMOjo training, and 12 ECMO specialists and 12 non-specialists that were assigned to the lecture group (See Figures 9 - 12 for details). No statistically significant differences were observed, although ECMOjo specialists had higher scores for the wet lab assessment. Results indicate that there is no difference in training for both novices and experts.

ScnPoints					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.398	1	.398	2.606	.114
Within Groups	6.407	42	.153		
Total	6.805	43			

Figure 9 – ECMO Specialists vs. Non-ECMO Specialists (Statistics)

ScnPoints					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	2.450	14	.175	1.165	.350
Within Groups	4.355	29	.150		
Total	6.805	43			

Figure 10 – Performance for Years ECMO (Statistics)

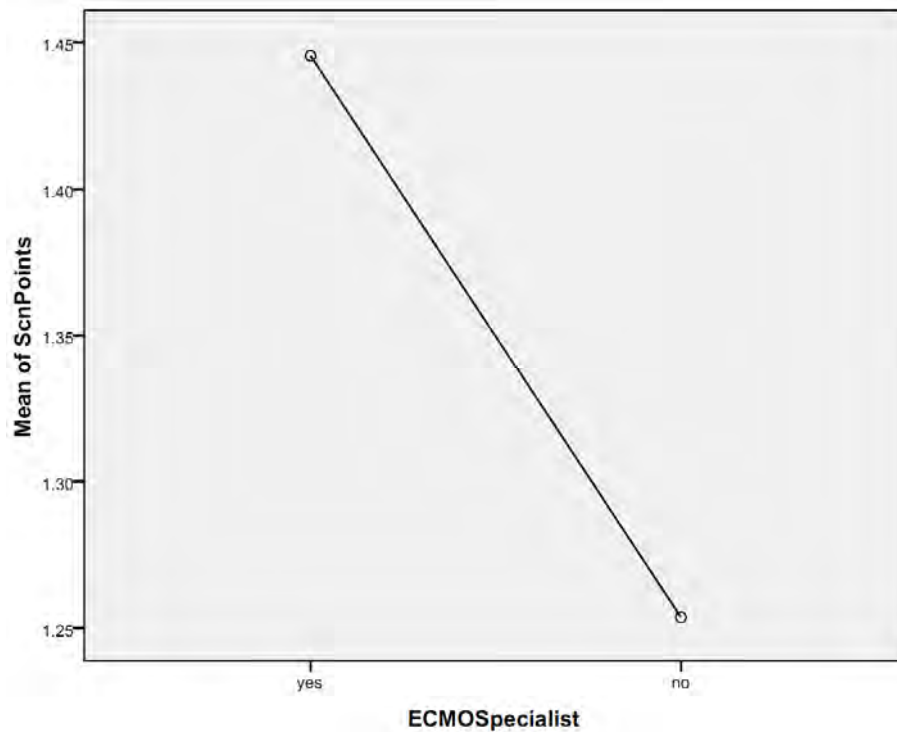


Figure 11 – ECMO Specialists vs. Non-ECMO Specialists (Graph)

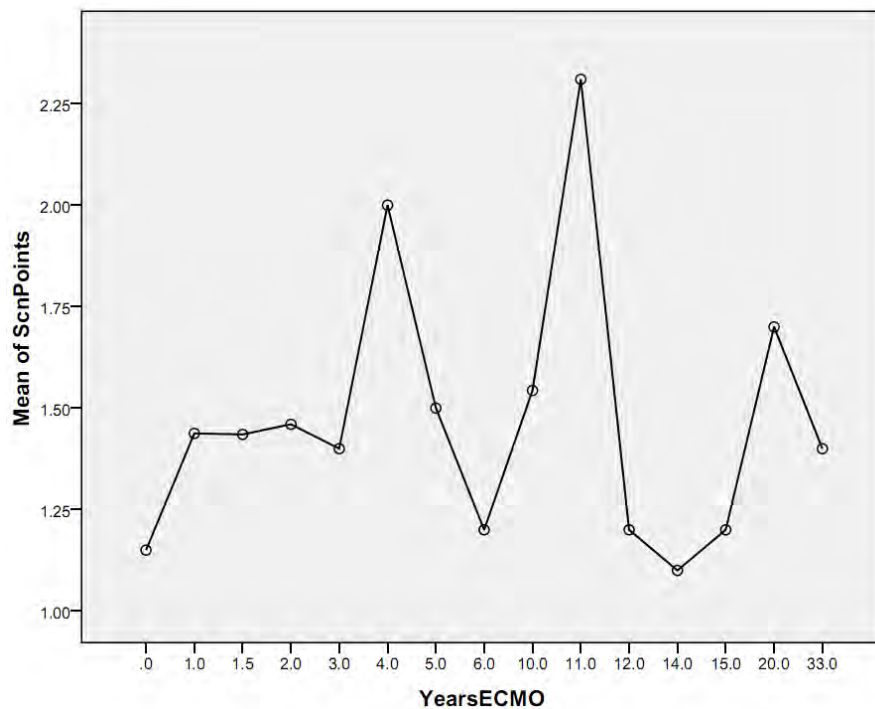


Figure 12 – Performance for Years ECMO (Graph)

Research Question Q4)

No statistically significant relationship between ECMOjo and wet-lab performances has been found. Please review Figure 13 for details.

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	29.333 ^a	33	.650
Likelihood Ratio	40.542	33	.172
Linear-by-Linear Association	1.339	1	.247
N of Valid Cases	42		

Figure 13 – Chi-square (Training x Performance)

Discussion

Results for the ECMO skills acquisition study indicate that ECMOjo is *equivalent* in training when compared to standard didactic classroom learning. No differences have been observed between groups trained with ECMOjo versus participants trained in the classroom. Also, ECMOjo has been shown to train both novices and experts equally.

We believe ECMOjo is a valuable addition to current state-of-the-art ECMO training practices. ECMOjo is a computer-based simulation model that can provide important cognitive skills

training and practice that is not possible in a classroom setting. With equality between ECMOjo and didactic training, it can be utilized instead of didactic training prior to the wet-lab experience. One of the postulated benefits of ECMOjo that can be explored with future research is to practice and train more difficult clinical and pump scenarios for ECMO providers. The simulator makes this possible. This would be more difficult to teach in a classroom setting. Future research could help to define the benefit of ECMOjo for more advanced training scenarios.

ECMOjo is postulated to reduce the need for animal laboratories for trained ECMO providers, who only require refresher training. The simulation can be run on any standard computing platform, including a PC or Macintosh computer, increasing access to training and likely improving patient care outcomes overall. ECMOjo should not replace but complement classroom-based, wet-lab, and animal-lab training. This study demonstrated that it can be used in place of didactic lecture, with no difference in learning outcomes for trained and untrained providers.

Conclusion

ECMOjo is an advanced simulator with anatomic, physiologic, and pharmacologic realism. The application has increased the applicability for medical simulations to provide advanced training in many areas of acute care medicine. For many years, physicians have depended on bedside patient interaction to impart knowledge to trainees. This concept has become less popular for initial training, with increased concerns over patient safety, and the difficulty of having a representative patient available for each diagnosis. The applicability of the simulator for ECMO training for low-volume centers is evident, especially where there is limited bedside experience. Likewise, the ethical imperative to use simulation in training whenever possible is an important concept, as patients are protected instead of being commodities in training

ECMOjo has been developed as an open source project and is available on SourceForge.net for download without charge. Both source code as well as binaries for end-users are available on the web site.

Acknowledgement

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Appendix A – ECMOjo Scenarios

ECMOjo Scenario – The circuit check

Description: The circuit check is to ensure the integrity of the circuit and to catch problems early or real time. This simulation represents a generic circuit and may not include all of the components used at your center.

Non default settings: none

4. The purpose of the circuit check is to ensure the integrity of the circuit and to catch problems early!
5. The check involves a close scrutiny of the circuit components from arterial to venous cannulas.
6. Find the arterial cannula at the patient's neck
7. Follow the arterial limb of the circuit tubing. This is where you check the connectors for clots, air, leaks, fibrin strands.
8. Find the oxygenator. This is where you check for air, clots/fibrin, secure gas line connection, open gas vent port, secure water heater connections, secure pressure/sample port connections, integrity.
9. Click on the Gas Blender
10. This is where you would check the gas source for function and connections to wall air and oxygen. Also check carbon dioxide or carbogen source if applicable.
11. Another part of the circuit check, is inspecting the connectors, stopcocks, and pigtails for cracks, leaks, clots/fibrin, air, security.
12. Click on the Pressure Monitor
13. Here you will verify pre and post membrane pressures and the transmembrane pressure. Inspect pressure transducers and cables.
14. Continue to inspect tubing between the oxygenator and the pump for kinks, clots/fibrin.
15. Continue on to the pump head or raceway, to check for air, function, sound, clots/fibrin, integrity.
16. Click on the Pump Control
17. This is where you would check the pump console for proper function, flow rate, RPMs, alarms, power source, battery supply.
18. Click on the Heater Controls
19. Check heater for proper function, alarms, water bath temperature, temperature set point, patient blood temp, patient temperature, power source, reservoir level, lines to oxygenator.
20. Continue to inspect venous line tubing, connectors, stopcock, pigtails, bladder for cracks, leaks, clots/fibrin, air, security.
21. Continue up to the venous cannula and check for position, bleeding, clots/fibrin, kinking, air, security to mattress.
22. Verify medications and volume infusions into the circuit.
23. And always make sure you have your tubing clamps and emergency back-up supplies.

24. ECMOism: “The best ECMO is boring ECMO”

ECMOJo Scenario – Coming off ECMO NOW!

Description: Steps to emergently come off of ECLS support.

Non default settings: none

10. ECMOism: “ECMO is 95% boredom, and 5% sheer terror”
11. You are now one elite 5% that will experience the terror of ECMO. If you can’t immediately see what’s causing all the alarms, what should you do?
12. A circuit check
13. Call for HELP!
14. You find the a catastrophic problem, and you must come off ECMO
15. Clamp the circuit ?
 - a. Roller pump = VBA (very bad accident)
 - i. Clamp Venous
 - ii. Unclamp Bridge
 - iii. Clamp Arterial
 - b. Centrifugal pump = ABV
 - i. Clamp Arterial
 - ii. Unclamp Bridge
 - iii. Clamp Venous
16. Increase the ventilator settings for additional support in respiratory cases. Click “emergency vent” button. In the simulation world, handbagging or institution of the emergency settings is accomplished in a single step.
17. Resuscitate the patient as needed
18. Do you need a surgeon?
19. If it involves the cannulas, the answer is yes.

ECMOJo Scenario – 5% Terror Time Tutorials – Situation 1: Accidental Arterial Decannulation

Description: There are four situations that you should recognize for coming off of ECMO emergently.

Non default settings: Arterial Cannula Leak. Hypovolemia. VA.

4. The bedside nurse is performing her patient assessment and you notice that her ID badge is under the arterial cannula. She raises her head after using the stethoscope and her badge catches and pulls on the arterial cannula.
5. Notice what alarms are ringing and the changes in physiologic parameters.
 - a. Blood dripping from neck

- b. Hypovolemia variable: CVP low, P1 pressure negative, BP low, tachycardic, flow low, desaturation
- 6. You can't handle this one by yourself. Call for help. ECMOism: "ECMO is a team effort"
- 7. At the bedside you would apply pressure to the cannulation site
- 8. Clamp the circuit ?
 - c. Roller pump = VBA (very bad accident)
 - i. Clamp Venous
 - ii. Unclamp Bridge
 - iii. Clamp Arterial
 - d. Centrifugal pump = ABV
 - i. Clamp Arterial
 - ii. Unclamp Bridge
 - iii. Clamp Venous
- 4. Increase the ventilator settings for additional support in respiratory cases. Click "emergency vent" button. In the simulation world, handbagging or institution of the emergency settings is accomplished in a single step.
- 9. Resuscitate the patient as needed
- 10. Don't forget to call the surgeon for fix to cannula.

ECMOJo Scenario – 5% Terror Time Tutorials – Situation 2: Large blood loss from circuit.

Description: There are four situations that you should recognize for coming off of ECMO emergently.

Non default settings: Cracked Pigtail. Hypovolemia.

- 11. In the ICU, large blood loss can be caused by a broken stopcock or cracked pigtail. The component will need to be exchanged urgently.
- 12. Notice what alarms are ringing and the changes in physiologic parameters.
 - a. Blood dripping from intervention site D.
 - b. Hypovolemia: CVP low, P1 pressure negative, BP low, high HR, then low HR, flow low, desaturation
- 13. You can't handle this one by yourself. Call for help.
- 11. Clamp the circuit ?
 - c. Roller pump = VBA (very bad accident)
 - i. Clamp Venous
 - ii. Unclamp Bridge
 - iii. Clamp Arterial
 - d. Centrifugal pump = ABV
 - i. Clamp Arterial
 - ii. Unclamp Bridge
 - iii. Clamp Venous
- 5. Increase the ventilator settings for additional support in respiratory cases. Click "emergency vent" button. In the simulation world, handbagging or institution of the

- emergency settings is accomplished in a single step.
14. Resuscitate the patient as needed
 15. Most times the stopcocks and pigtails will crack or break and create a small blood leak or minor venous air entrainment. The component will need to be exchanged under non-emergent controlled conditions.

ECMOjo Scenario – 5% Terror Time Tutorials – Situation 3: Pump Failure

Description: There are four situations that you should recognize for coming off of ECMO emergently.

Non default settings: Pump off.

5. Notice what alarms are ringing and the changes in physiologic parameters.
 - a. Pump not turning, and pump control screen blank
 - b. Low patient saturation, BP low, high HR, then low HR
6. You can't handle this one by yourself. Call for help.
7. Clamp the circuit ?
 - a. Roller pump = VBA (very bad accident)
 - i. Clamp Venous
 - ii. Unclamp Bridge
 - iii. Clamp Arterial
 - b. Centrifugal pump = ABV
 - i. Clamp Arterial
 - ii. Unclamp Bridge
 - iii. Clamp Venous
8. Increase the ventilator settings for additional support in respiratory cases. Click "emergency vent" button. In the simulation world, handbagging or institution of the emergency settings is accomplished in a single step.
9. Resuscitate the patient as needed
10. At the bedside, consider using the handcrank until the problem is solved.

ECMOjo Scenario – 5% Terror Time Tutorials – Situation 4: Air in arterial limb of circuit

Description: There are four situations that you should recognize for coming off of ECMO emergently.

Non default settings: Arterial Bubbles. Pump Off.

1. Notice what alarms are ringing and the changes in physiologic parameters.
 - a. Bubble detector alarming
 - b. Pump stopped
 - c. Low patient saturation, BP low, high HR, then low HR
2. You can't handle this one by yourself. Call for help.

3. Clamp the circuit ?
 - a. Roller pump = VBA (very bad accident)
 - i. Clamp Venous
 - ii. Unclamp Bridge
 - iii. Clamp Arterial
 - b. Centrifugal pump = ABV
 - i. Clamp Arterial
 - ii. Unclamp Bridge
 - iii. Clamp Venous
4. Increase the ventilator settings for additional support in respiratory cases. Click “emergency vent” button. In the simulation world, handbagging or institution of the emergency settings is accomplished in a single step.
5. Resuscitate the patient as needed
6. Open the bridge to recirculate the air to the venous side
7. Reset the bubble detector
8. Restart the pump at the pump controls
9. What other areas of the circuit can lead to air in the arterial limb?
 - a. 1) Venous limb of circuit: catastrophic introduction of venous air.
 - b. 2) Oxygenator: fiber rupture of membrane.
 - c. 3) Connectors: incomplete air removal during prime

ECMOjo Scenario – Sweep Gases 1

Description: Adjusting the FiO_2 delivered to the oxygenator.

Non default settings: None

1. Click on the gas blender
2. This device controls the gases delivered to the oxygenator.
3. Increase the level of oxygen to the membrane. (turn FiO_2 knob).
4. Notice the changes on the CDI monitor’s post membrane values.
5. The CDI PaO_2 increased
6. The CDI PO_2 increased, but the CDI sO_2 remains at 100%. The oxygen content CaO_2 of the blood exiting the membrane remains the same. Why?
7. The CaO_2 is a function of Hgb concentration and oxygen saturation. If the Hgb concentration stays the same, and oxygen saturation remains 100%, then the oxygen content should stay the same.
8. What happens to the patient’s saturations?
9. What is the best way to increase oxygen delivery? a) Increasing sweep gas flow to the oxygenator; b) increasing vent settings; or c) changing pump flow?
10. Oxygen delivery is a function of cardiac output and CaO_2 . With VA ECMO, turn up the flow. Same with VV ECMO, except watch out for recirculation (more later)

ECMOjo Scenario – Sweep Gases 2

Description: Adjusting the total sweep gas delivered to the oxygenator.

Non default settings: None

1. Click on the gas blender.
2. This device controls the gases delivered to the oxygenator.
3. Increase the total sweep gas to the membrane.
4. Notice the changes on the CDI monitor's post membrane values
5. The CDI PaCO₂ decreased rapidly and pH increased.
6. The CDI PaO₂ and sO₂ remained unchanged.
7. What happens to the patient's ABG?
8. Patient ABG PaCO₂ decreases, pH increases, and PaO₂ stays the same.
9. What is the best way to remove CO₂?
 - a. increasing sweep gas flow to the oxygenator?
 - b. increasing vent settings?
 - c. changing pump flow?
10. CO₂ removal is a function of total sweep gas flow through the oxygenator. With VA and VV ECMO, turn up sweep gas flow to remove CO₂.

ECMOjo Scenario – Temperature Control

Description: Functions of the Heater

Non default settings: Heater broken (temp at 35 degrees)

1. Click on the heater control.
2. The heater unit is a very efficient way to maintain normothermia.
3. Due to the large tubing surface area, significant heat loss may result if the heater unit malfunctions.
4. With significant hypothermia, note the impact on some of the coagulation values.
5. A DIC picture emerges. The PT, PTT and ACT increases. Fibrinogen decreases.
6. If you suspect a heater failure, check the water tube connections, power cord attachment and temperature set point. If everything checks out okay, the unit may have failed. Replace the unit.

ECMOjo Scenario – VA ECMO Pump Flow

Description: Physiologic and ECMO variables impacted by VA pump flow

Non default settings: VA

Click on the pump control

Notice the pump is rotating. To simplify the simulation, the pump control panel only shows the flow rate without RPM.

Turn the knob to increase the pump flow.

What changes do you see when the pump flow is increased?

Patient: Blood pressure and SaO₂ increases. Mixed venous saturation increases.

Pressure Monitor: Venous pressure becomes more negative and pre and post membrane pressure increase

ECMOjo Scenario – VV ECMO Pump Flow

Description: Physiologic and ECMO variables impacted by VV pump flow

Non default settings: VV

1. Click on the pump control
2. Notice the pump is rotating. To simplify the simulation, the pump control panel only shows the flow rate without RPM.
3. Turn the knob to decrease the pump flow by 50 ml to approx 0.55. (rotate)
4. What changes do you see when the pump flow is decreased by 50 ml?
5. Some of the changes:
 - a. Blood pressure minimal change
 - b. P1 minimal change
 - c. P2/P3 no change
 - d. SaO₂ decreases,
 - e. SvO₂ decreases
6. On VV, oxygen delivery is affected by flow. Less flow, less oxygen delivery. More flow, more oxygen delivery, but only up to a certain point (more later)
7. Turn the knob to increase the pump flow by 200 ml to approx 0.75. (rotate)
8. What changes do you see when the pump flow is increased significantly?
9. Some of the changes:
 - a. Blood pressure minimal change
 - b. P1 becomes more negative
 - c. P2/P3 small increases
 - d. SaO₂ decreases
 - e. SvO₂ increases
10. What does this suggest?
11. Recirculation

ECMOJo Scenario – Circuit Failure

Description: Events associated with a circuit failure.

Non default settings: none

1. One of the purposes of a circuit check is to look for nasty clots growing silently in the circuit.
2. Where are the common areas for these clots to form?
3. Oxygenator, Heat exchanger (if applicable), Connectors, Bridge
4. Review the HEME and ACT lab values?
5. What lab values are concerning for circuit failure?
6. Decreases in platelets, fibrinogen. Increases in ACT, PTT, PT
7. You have given blood products but your lab values do not correct.
8. Looks like the circuit is consuming blood products. What would you recommend at this time?
9. Consider changing the circuit. Select the patient, and click on “Change circuit”
10. If your assessment was correct, the lab values will normalize.

ECMOJo Scenario –Air in the Venous Limb

Description: Actions to take when air is seen in the venous limb of the circuit.

Non default settings: Venous Bubbles. Quadrox D Oxygenator.

1. While performing your hourly circuit check you notice some air bubbles streaming down the venous side of the circuit.
2. What decision do you need to make immediately?
3. Is this a “Terror Time” moment? Or is there time to triage the situation and get coffee?
4. Let’s pretend that there isn’t much venous air. What sites are the most likely sources for venous air?
5. Most likely sources for venous air are:
 - a. Entrainment air from venous catheter
 - b. Open or cracked stopcock on the venous side
 - c. Air introduced from medications infusing into the patient via a central venous line
6. After you have made sure the patient is safe, remove air from system.
7. Identify and fix cause, if possible

ECMOJo Scenario – Oxygenator Failure

Description: Identifying an oxygenator failure

Non default settings: Sweep gas higher. Sweep FiO₂ higher. Lab-component-heme-* Higher Pre membrane pressure. Higher Post membrane pressure.

1. The oxygenator can be a “black hole” for clotting factors.
2. This oxygenator is beginning to concern you. Can you find the warning signs?
3. Pressure monitor changes: A higher P2, leading to a higher transmembrane gradient
4. Heme Lab value changes: Decreases in platelets, fibrinogen. Increases in ACT, PTT, PT.
5. Post Membrane blood gases and sweep gas settings:
 - a. Slight increases in post membrane PaO₂ and PaCO₂
 - b. Increased sweep gas settings
 - i. Sweep to 2.3 liters
 - ii. FiO₂ to 85%
6. You have given blood products but your lab values do not correct.
7. Looks like there may be a clot in the oxygenator that is consuming your blood products. What would you recommend at this time?
8. You strongly encourage an oxygenator change as soon as possible. ECMOism: “There is no time like the present”
9. Click on patient, then the “change circuit” button.

ECMOjo Scenario – Oxygenator Rupture

Description: Description of events that occur with a oxygenator rupture. Non default settings: Oxygenator Component Broken.

1. TERROR TIME due to a ruptured membrane
2. Next time change the oxygenator before it is too late.

ECMOjo Scenario – High Pre-Membrane Pressure

Description: Identifying the cause of a high pre-membrane pressure

Non default settings: High Pre-membrane pressure

1. You are performing your hourly circuit check and your keen senses tell you that the pre-membrane pressure is rising.
2. What would you check?
3. Check downstream (forward toward patient) from monitoring site
4. Click pressure monitor
5. Notice there is no change in the Post membrane pressure (P3)
6. Click patient, then “check cannula site” button
7. No problems with the arterial cannula noted.
8. Isolated high pre-membrane pressure suggests a problem inside your oxygenator

ECMOJo Scenario – Negative Venous Pressure

Description: Identifying the cause of a very negative venous/bladder pressure

Non default settings: Hypovolemia, Lab-component-Heme-Hemoglobin, lab-image-x-ray

9. You are performing your hourly circuit check and your sharp memory tells you that the venous pressure is becoming increasingly negative.
10. What would you check?
11. Check upstream (back toward patient) from monitoring site
12. Click patient, then “check cannula site” button
13. Check venous cannula for kink
14. Check IMG, then x-ray
15. Check venous cannula for position
16. Click patient, then “check sedation” button
17. If the patient is active, the catheter may have changed position. Consider sedation.
18. Do the physiologic variables suggest hypovolemia?
 1. Physiologic parameters (HR high, CVP low)
19. If the patient is hypovolemic and has a low Hgb, you can give PRBC.
 1. Hgb low
20. Click on Intervention A, then blood cells button
21. Isolated high pre-membrane pressure suggests a problem upstream (back toward patient) from monitoring site

ECMOJo Scenario – High Post-Membrane Pressure

Description: Identifying the cause of a high post-membrane pressure

Non default settings: Scenario one (arterial kink).

1. You are performing your hourly circuit check and with your keen sight you notice that the post-membrane pressure has risen
 - a. Show higher P3 pressure
 - b. Show higher P2 pressure
2. What would you check?
3. Check downstream (forward toward patient) from monitoring site
4. Click patient, then “check cannula site” button
5. Check arterial cannula for kink,
6. Check IMG, then x-ray
7. Check arterial cannula’s position
8. If the patient is active, the catheter may have changed position. Consider sedation.
9. Click patient, then “check sedation” button
10. In VA ECMO, a high afterload from hypertension can increase post membrane pressures. Consider treatment with an antihypertensive.

11. Isolated high post-membrane pressure suggests a problem downstream (forward toward patient) from monitoring site

ECMOJo Scenario – ECMOisms

Description: The unofficial laws of ECMO, by J Devn Cornish, MD

Non default settings: none

5. There's no ECMO, like no ECMO.
6. ECMO is a team effort
7. Everybody loves everybody, but nobody trusts anybody
8. ECMO is 95% boredom, and 5% sheer terror.
9. Any fool can do ECMO when everything is going well, but only a real fool would do ECMO when things aren't going well.
10. There is no time like the present.
11. The enemy of good is better
12. It's not over till it's over
13. The best ECMO is boring ECMO

Appendix B – Circuit Check & Wet Lab Scenarios

ECMOjo Circuit Check

Participant # _____

Patient Monitor: Baseline (Baseline.tnd)

- ☐ Flashlight
 - ☐ Venous Cannula
 - Bleeding
 - Position/landmarks
 - Clots/fibrin
 - ☐ Bridge
 - Stopcocks off to circuit or line clamped
 - Flush per policy
 - ☐ Connectors
 - Cracks
 - Tubing security
 - Clots/fibrin
 - ☐ Stopcocks
 - Off to circuit and capped
 - Tight connection to luer lock
 - ☐ Bladder
 - Volume
 - Air
 - Clots
 - ☐ **Roller Pump**
 - Tubing integrity
 - Air
 - Blood flow setting – (*occlusion setting*)
 - ☐ **Centrifugal Pump**
 - Air
 - Blood flow/RPM setting
 - Gel
 - ☐ Oxygenator
 - Clots
 - Leaks
 - Vent port open
 - Sigh
 - ☐
 - ☐ Heater
 - Water bath temperature
 - Patient temperature
 - Water level
 - ☐ Gas Flowmeter
 - Tubing connections to flowmeter and oxygenator
 - Gas source connections to wall outlets
 - Sweep and FiO2 settings
 - ☐ Blood Flowmeter
 - Correct direction of blood flow
 - ☐ Arterial Cannula
 - Bleeding
 - Position/landmarks
 - Clots/fibrin
 - ☐ Clamps available at bedside
 - ☐ Hospital generator electrical outlets/UPS utilized
- Emergencies
- ☐ Clamp patient off circuit
 - VBA or AVB
 - ☐ Call for help
 - RN
 - RT
 - MD
 - Perfusionist
 - Surgeon
 - ☐ Emergency ventilator settings
 - ☐ Code drugs
 - ☐ Blood bank

Scenario 1

Wet lab Scenario – Gas Failure

Initial Set-Up for Student (t=0)

VS Trend: Baseline: 30 seconds. Scenario: 31+ seconds

Action: Before start - Gas line is disconnected at the blender or oxygenator or connect gas line to exhaust port

Trigger: Alarms

History: ECMO has just been initiated for this infant with meconium aspiration and everyone is starting to clean up after the cannulation. You are just starting to catch up with your charting.

The second set of gases have returned.

ECMO Mode: VA or VV

Patient: (GF1 SvO2.tnd)

Temp 37

HR 140 100 66

BP 60/40 (47) 36/6 (23)

CVP 4

Saturation 93% 69%

SvO2 79% 51%

(if SvO2 function is used on Sim monitor)

CDI 7.27 / 75 / 39 / 18 / BD 4

H/H 39% / 13

SvO2 51%

Blood gas - Baby Boy Rap

Patient: 7.28 / 71 / 47 / 16 / BD 5

Pre Memb: 7.23 / 79 / 32 / 14 / BD 7

Post Memb: 7.29 / 67 / 41 / 18 / BD 4

Pressures: Venous 0 Pre-memb 149 Post-memb 145

Available data

- Physical Exam: Quiet. No spontaneous movements. Mottled. Dusky. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill delayed. Extremities cool
- Color blood in circuit tubing – same color
- CXR: Ordered, but tech is busy in the ER with a code
- Chem: Previous labs normal. Sample sent to lab. Results pending.
- Heme: Previous labs normal. Sample sent to lab. Results pending.
- ACT: 180 sec

Participant # _____

Scenario 1

Wet lab Scenario – Gas Failure

Scoring

Time to accomplish: 120 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Recognize increased CO₂
- ☐ Increases sweep gas
- ☐ Evaluates CDI (if applicable)
- ☐ Call for help
- ☐ Initiates emergency ventilator settings
- ☐ Circuit check
- ☐ Checks oxygenator for clots
- ☐ Checks gas line for disconnection at source
- ☐ Checks gas line for kinks
- ☐ Reconnect gas tubing

Discouraged interventions

- ☐ Come off ECMO

COMMENTS

Scenario 2

Wet lab Scenario – Heater Failure

Initial Set-Up for Student (t=0)

VS Trend: Baseline - 30 seconds. Scenario – 31+ seconds
Action: Before start - Turn off heater. Unplug.
Trigger: Monitor

History: 2 month old former premature infant with RSV pneumonia.
You are getting back from a break and no events occurred while you were gone.

ECMO Mode: VA or VV

Patient: (HF1 SvO2.tnd)
Temp 35.9 34
HR 120 81
BP 71/42 (52) 75/46 (56)
CVP 5
Saturation 94%
SvO2 75% 69%
(if SvO2 function is used on Sim monitor)

CDI 7.43 / 39 / 309 / 23 / BE 2
H/H 39% / 13
SvO2 69%

Blood gas – ordered and results pending.

Pressures Venous -9 Pre-memb 130 Post-memb 120

Available data

- Physical Exam: Quiet. Pale. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill delayed. Extremities cool
 - Color blood in circuit tubing – color differentiation seen
 - CXR: Ordered, but tech is busy in the ER with a code
 - Chem: Morning lab sample sent to lab. Results pending.
 - Heme: Morning lab results. CBC normal.
- PT slightly elevated to 22. PTT increased from 82 to 101
- ACT: Increased from 179 to 193 sec

Scenario 2

Wet lab Scenario – Heater Failure

Scoring

Time to accomplish: 180 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Recognize hypothermia
- ☐ Recognize hypothermia induced bradycardia
- ☐ Maintain normothermia
 - Blankets or warmer blanket or thermo-gel blankets
 - Over bed warmer
- ☐ Circuit check
- ☐ Call for help
- ☐ Go to heater
- ☐ Check heater switch
- ☐ Check heater plug
- ☐ Check heater temperature set point
- ☐ Check heater hose valves

Discouraged interventions

- ☐ Come off ECMO

COMMENTS

Scenario 3

Wet lab Scenario – Pump Failure

Initial Set-Up for Student (t=0)

VS Trend: Baseline: 30 seconds. Scenario: 31+ seconds

Trigger: At 0:25 distract student, have mole turn off pump

History: 1 month old with H1N1 pneumonia and myocarditis.
There are heavy rain and winds due to a storm. Multiple power surges have been disrupting your shift. A brief black out has just occurred.

ECMO Mode: VA

Patient: (NoFlow SvO2.tnd)

Temp 37

HR 130 60 50

BP 68/38 (48) 36/6 (16)

CVP 6 0

Saturation 96% 44%

SvO2 79% 69%

(if SvO2 function is used on Sim monitor)

CDI 7.45 / 37 / 318 / 24 / BE 2

H/H 39% / 13

SvO2 69%

Blood gases – Baby Girl Hula

Patient: 7.26 / 78 / 41 / 14 / BD 6

Pre Memb: 7.19 / 81 / 30 / 11 / BD 8

Post Memb: 7.45 / 38 / 314 / 22 / BE 1

Pressures Venous -9 Pre-memb 130 Post-memb 120

Available data

- Physical Exam: Quiet. No spontaneous movements. Mottled. Cyanotic. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill delayed. Extremities cool
- Color blood in circuit tubing – equal
- CXR: ask for reason. Results: normal
- Chem: Previous labs normal. Sample sent to lab. Results pending.
- Heme: Previous labs normal. Sample sent to lab. Results pending.
- ACT: 180 sec

Scenario 3

Wet lab Scenario – Pump Failure

Scoring

Time to accomplish: 90 seconds

Dies at 90 sec

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Orders CXR is to look for pneumothorax or pneumomediastium
- ☐ Circuit check
- ☐ Recognizes pump failure
- ☐ Call for help
- ☐ Clamp off circuit
- ☐ Emergency vent settings
- ☐ Check pump switch
- ☐ Check plug
- ☐ Get hand crank
- ☐ Verbalizes with hand crank that the SvO2 is used to monitor = adequate flow?

Discouraged interventions

- ☐ Does not come off circuit
- ☐ Attempts to hand crank without coming off circuit

COMMENTS

Scenario 4

Wet lab Scenario – Circuit Failure / DIC

Initial Set-Up for Student (t=0)

VS Trend: Continuous

Action: Draw clots

Set sweep at 4 liters and FiO₂ at 0.70

Blood at cannula site

Trigger: Give Children's Hospital of ECMOjo ABG & HEME results
for Baby Boy Hip to student

History: 2 month old with a viral myocarditis. Day 5 of the run. You have just
started your shift and some of the morning lab results are now available.

ECMO Mode: VA

Patient: (no trend)

Temp 37

HR 130

BP 68/38 (48)

CVP 5

Saturation 97%

SvO₂ 65% (if SvO₂ function is used on Sim monitor)

CDI 7.45 / 37 / 318 / 24 / BE 2

H/H 39% / 13

SvO₂ 71%

Available data

Physical Exam:

Quiet. Pink. Blood oozing from cannula site. BS equal. Heart sounds normal. Abdomen soft.
Peripheral refill 3 sec. Extremities warm to wrist and ankles.

Blood gas – Baby Boy Hip

Pressures Venous -12

Pre-memb 194

Post-memb 189

Color blood in circuit tubing – color differentiation seen

CXR: Ordered. Still waiting for the tech.

Chem: Sent. Results pending.

Heme: Results reported.

ACT: 171 to 188 sec

Scenario 4

Wet lab Scenario – Circuit Failure / DIC

Scoring

Time to accomplish: 300 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Recognize abnormal labs
- ☐ Recognize trend
- ☐ Give platelets
- ☐ Give FFP or cryo
- ☐ Order additional labs after blood products
- ☐ Gives additional blood products
- ☐ Circuit check
- ☐ Check for clots
- ☐ Check oxygenator
- ☐ Change circuit.

Discouraged interventions

- ☐ Come off ECMO

COMMENTS

Scenario 5

Wet lab Scenario – Oxygenator Failure

Initial Set-Up for Student (t=0)

VS Trend: Continuous

Action: Draw clots

Adjust sweep gas to 2.5 lpm and FiO₂ to 0.70

membrane
Adjust pre membrane pressure zero calibration to have a large delta P across

Trigger: Give Children's Hospital of ECMOjo ABG & HEME results for Baby Girl Disco to student

History: 2 month old with a viral myocarditis. Day 5 of the run. You have just started your shift. No mechanical problems have been encountered with the circuit, but the off going ECMO specialist was very tired and mentioned that there were some new clots in the oxygenator. Some of the morning lab results are now available.

ECMO Mode: VA

Patient: (OF1 SvO₂.tnd)

Temp 37

HR 130

BP 72/38 (49)

CVP 5

Saturation 97%

SvO₂ 66% (if SvO₂ function is used on Sim monitor)

CDI 7.33 / 52 / 121 / 21 / BE 2

H/H 36% / 12

SvO₂ 66%

Blood gas – Baby Girl Disco

Pressures Venous -9 Pre-memb 281 Post-memb 149

Available data

- Physical Exam: Quiet. Pink. Blood oozing from cannula site. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill 3 sec. Distal extremities cool.
- Color blood in circuit tubing – color differentiation seen
- Oxygenator – clots seen
- Sweep gas – 2.5 lpm, FiO₂ = 0.7
- CXR: ordered, but tech is busy in the CVICU with a code
- Chem: Sent. Results pending.
- Heme: Report results from Baby Girl Disco
- ACT: Report results from Baby Girl Disco

Scenario 5

Wet lab Scenario – Oxygenator Failure

Scoring

Time to accomplish: 300 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Recognize abnormal labs
- ☐ Recognize trend in post membrane ABG PCO₂ and PO₂
- ☐ Adjust sweep gases
- ☐ Calls for help
- ☐ Circuit check
- ☐ Check oxygenator for clots
- ☐ Recognize abnormal trans-membrane gradient
- ☐ Adjusts heparin rate (lower)
- ☐ Gives blood products (platelets, FFP, cryo)
- ☐ Identify oxygenator failure

Discouraged interventions

- ☐ Come off ECMO
- ☐ Increase heparin rate

COMMENTS

Scenario 6

Wet lab Scenario – Venous Air

Initial Set-Up for Student (t=0)

VS Trend: Continuous

Trigger: (at any time) Inject air into reservoir or

Place punctured cap on stopcock or pigtail. Withdraw volume to make venous pressures more negative

History: Day 3 for a newborn infant with Group B sepsis. Everything has been going well and its been 94% boredom. The patient is awake and responsive to environment stimulation. It is time for your hourly circuit check.

ECMO Mode: VA or VV

Patient: (no trend)

Temp 37.1

HR 140

BP 72/38 (48)

CVP 4

Saturation 96%

SvO2 71% (if SvO2 function is used on Sim monitor)

CDI 7.46 / 38 / 312 / 24 / BE 4

H/H 36% / 12

SvO2 71%

Blood gas – Sent and results are pending

Pressures: Venous -25 Pre-memb 130 Post-memb 120

Available data

- Physical Exam: Quiet. Pink. Blood oozing from cannula site. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill 3 sec. Extremities warm to wrist and ankles.
- Color blood in circuit tubing – color differentiation seen
- Oxygenator – no clots seen
- CXR: Ordered, but tech is busy in the CVICU with a code
- Chem: Sent. Results pending.
- Heme: Sent. Results pending.
- ACT: 176 sec (stable)

Scenario 6

Wet lab Scenario – Venous Air

Scoring

Time to accomplish: 300 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Circuit check
- ☐ Calls for help
- ☐ Recognizes air in venous circuit
- ☐ Checks arterial side of circuit
- ☐ Determines if emergency or not an emergency
- ☐ Check catheters
- ☐ Check stopcocks and other connectors
- ☐ Check medications infusing into central catheters to circuit
- ☐ Check medications infusing into central catheters to patient
- ☐ Verbalizes: Need to remove air

Discouraged interventions

- ☐ Come off ECMO

COMMENTS

Scenario 7

Wet lab Scenario – Bubble Detector Alarm

Initial Set-Up for Student (t=0)

Baseline: 30 seconds. Coupled PVC start at 0:45

Action: Inject air into system post oxygenator at 0:28 minutes

History: 1 month old with aspiration pneumonia and ARDS. Today is day 7 of the ECMO run. The circuit was change 1 hour ago due to circuit failure.

ECMO Mode: VV

Patient: (NoFlow SvO2.tnd)

(NoFlow SvO2 NoBub.tnd - no bubble dectector – 30 sec delay in physiologic parameter changes)

Temp 37

HR 150 80 (with coupled PVC)

BP 68/38 (48) 47/17 (27)

CVP 4 5

Saturation 93% 53%

SvO2 75% 45%

(if SvO2 function is used on Sim monitor)

CDI 7.45 / 37 / 318 / 24 / BE 2

H/H 39% / 13

SvO2 72%

Blood gases Baby Girl Tango

Pressures: Venous 5 Pre-memb 54 Post-memb 51

Available data

- Physical Exam: Quiet. No spontaneous movements. Mottled. Cyanotic. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill delayed. Extremities cool
- Color blood in circuit tubing – color differentiation seen
- CXR: ordered, but tech is busy and not answering their page
- Chem: Previous labs normal. Sample sent to lab. Results pending.
- Heme: Previous labs normal. Sample sent to lab. Results pending.
- ACT: 180 sec

Scenario 7

Wet lab Scenario – Bubble Detector Alarm

Scoring

Time to accomplish: 60 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Recognizes pump is off
- ☐ Recognized arterial bubble detector alarm
- ☐ Clamps off circuit
- ☐ Emergency vent settings
- ☐ Calls for help
- ☐ Circuit check
- ☐ Checks oxygenator
- ☐ Checks all connections on arterial side
- ☐ Checks for air at arterial side clamp
- ☐ Checks venous side
- ☐ CPR (Late addition - do not include in grading, but teaching point)

Discouraged interventions

- ☐ Attempts to hand crank

COMMENTS

Scenario 8

Wet lab Scenario – Accidental Arterial Decannulation (Hypovolemia)

Initial Set-Up for Student (t=0)

VS Trend: Baseline - 30 seconds; Trend 30+ seconds

Action: Gauze with blood at cannulation site. Push blood.

Take fluid out of bladder to create a more negative venous pressure

History: Day 1 for a 2 month old who had a witnessed arrest on the floor. Visitor with many dangling pieces of jewelry just left the bedside after giving the patient a kiss

ECMO Mode: VA

Patient: (Hypovolemia2 SvO2.tnd)

Temp 37

HR 140 50

BP 68/44 (52) 44/20 (28)

CVP 4 0

Saturation 96% 59%

SvO2 79% 43%

(if SvO2 function is used on Sim monitor)

CDI 7.45 / 37 / 318 / 24 / BE 2

H/H 39% / 13

SvO2 52%

Blood gases: Blood gas machine in calibration mode. Results pending.

Pressures: Venous -15 Pre-memb 160 to 100 Post-memb 154 to 95

Flow Decreases (depends on amount of volume removed & servo-reg)

Available data

- Physical Exam: Quiet. No spontaneous movements. Mottled. Cyanotic. BS equal. Heart sounds normal. Abdomen soft. Peripheral refill delayed. Extremities cool
- Color blood in circuit tubing – color differentiation seen
- CXR: ordered, but tech is busy and not answering their page
- Chem: Previous labs normal. Sample sent to lab. Results pending.
- Heme: Previous labs normal. Sample sent to lab. Results pending.
- ACT: 180 sec

Scenario 8

Wet lab Scenario – Accidental Arterial Decannulation (Hypovolemia)

Scoring

Time to accomplish: 60 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Give volume
- ☐ Circuit check
- ☐ Recognizes bleeding at cannulation site
- ☐ Verbalizes arterial versus venous decannulation
- ☐ Apply pressure to site
- ☐ Call for help
- ☐ Clamp off circuit
- ☐ Emergency vent settings
- ☐ Resuscitation of patient
- ☐ Call surgeon

Discouraged interventions

- ☐ Attempts to hand crank

COMMENTS

Scenario 9

Wet lab Scenario – High Post membrane pressure

Initial Set-Up for Student (t=0)

VS Trend: Baseline 30 seconds. Trend 30+ seconds.

Prep: Hoffman clamp on arterial tubing and
Adjust pressure zero calibration point higher on post membrane,
just below alarm limit

Action: Add volume at 0:28 seconds raise membrane pressures, and to
make alarm sound

History: Day 3 for a 2 month old who presented with V-tach unresponsive to
medical intervention. Found to have TAPVC. He is awake, but sedated, calm
and quiet. The nurse has just completed his assessment with a diaper change.

ECMO Mode: VA

Patient: (ArtCanKink1 SvO2.tnd)

Temp 37.2

HR 130 160

BP 70/42 (51) 48/20 (29)

CVP 5

Saturation 95% 83%

SvO2 75% 60%

(if SvO2 function is used on Sim monitor)

CDI 7.45 / 37 / 318 / 24 / BE 2

H/H 35% / 12

SvO2 52%

Blood gases: Sample sent. Results still pending

Pressures: Venous -2 Pre-memb 130 to 338 Post-memb 120 to 359

Flow Decreases (depends on amount of volume added & servo-reg)

Available data

- Physical Exam: Sedated. Quiet. Mottled. Dusky. BS equal but course. Heart sounds normal. Abdomen soft. Peripheral refill 4 to 5 sec. Extremities cool.
- Color blood in circuit tubing – color differentiation seen
- CXR: Taken. Radiologist calls back and says that shorter catheter appears bent.
- Chem: Previous labs normal. Sample sent to lab. Results pending.
- Heme: Previous labs normal. Sample sent to lab. Results pending.
- ACT: 176 sec

Scenario 9

Wet lab Scenario – High Post membrane pressure

Scoring

Time to accomplish: 60 seconds

Stop assessment when instructor gives verbal cues to the participant

Appropriate interventions

- ☐ Gives volume
- ☐ Orders chest X-ray
- ☐ Recognizes problem is downstream to the oxygenator
- ☐ Circuit check
- ☐ Calls for help
- ☐ Checks oxygenator
- ☐ Checks catheters
- ☐ Adjusts arterial cannula
- ☐ Assess activity level
- ☐ Calls surgeon

Discouraged interventions

- ☐ Comes off ECMO
- ☐ Attempts to hand crank

COMMENTS

Acronyms

• ACTH	-	adrenocorticotrophic hormone
• ALDO	-	aldosterone
• AOC	-	artificial oxygen carrier
• CO	-	cardiac output
• DOD	-	Department of Defense
• ECLS	-	extracorporeal life support
• ECMO	-	extracorporeal membrane oxygenation
• ECMOjo	-	computer simulation model for patient physiologic variables and ECMO pump biomechanical data
• ETS	-	ECMO Transport Sled
• HBOC	-	hemoglobin based oxygen-carrying solution
• FAA	-	Federal Aviation Administration
• KMCWC	-	Kapi'olani Medical Center for Women and Children
• MAP	-	mean arterial pressure
• NICU	-	Neonatal Intensive Care Unit
• PICU	-	Pediatric Intensive Care Unit
• PRA	-	plasma rennin activity
• pVP	-	plasma vasopressin
• RAP	-	right arterial pressure
• RBF	-	regional blood flow
• TAMC	-	Tripler Army Medical Center
• UH	-	University of Hawaii
• UPMC	-	University of Pittsburgh Medical Center
• VP	-	vasopressin